

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: EVOLUS INC. SECURITIES
LITIGATION

**MEMORANDUM
OPINION & ORDER**

20 Civ. 8647 (PGG)

PAUL G. GARDEPHE, U.S.D.J.:

This is a consolidated class action brought on behalf of purchasers of Defendant Evolus, Inc.’s common stock between February 1, 2019 and July 6, 2020 (the “Class Period”).

As alleged in the Amended Class Action Complaint, Evolus is a “medical aesthetics” company. Its only product is an “injectible botulinum neurotoxin” (“BTX”) which is sold under the brand name Jeuveau and used to treat wrinkles. (Am. Cmplt. (Dkt. No. 70) ¶ 2) (Id.) Jeuveau competes with BOTOX, a similar product manufactured by Allergan plc.

Evolus’s involvement with Jeuveau began in 2013, when it purchased an exclusive license to develop the drug from Daewoong Pharmaceuticals, a South Korean pharmaceutical company. (Id. ¶ 3) Allergan has an analogous partnership with Medytox, another South Korean pharmaceutical company, which also produces a BTX product. (Id. ¶ 48)

On January 25, 2019, Allergan and Medytox filed a complaint with the U.S. International Trade Commission (“ITC”) alleging that a former Medytox employee had misappropriated Medytox’s proprietary BTX strain and manufacturing process and delivered them to Daewoong, which had used these proprietary materials to manufacture Jeuveau. (Id. ¶¶ 6, 8) On July 6, 2020, an ITC administrative law judge issued a Final Initial Determination (“FID”) in which he concluded that Daewoong had in fact misappropriated Medytox’s proprietary materials and used them to manufacture Jeuveau. The ITC administrative law judge recommended a ten-year ban on the importation and marketing of Jeuveau in the United States. (Id. ¶ 21)

The Amended Complaint alleges that Defendant Evolus, Evolus's parent company Defendant Alphaeon Corporation,¹ and certain of Evolus's senior officers and directors issued false and misleading statements during the Class Period, "represent[ing] to investors that [Allergan and Medytox's] allegations [in the ITC litigation] had no merit," and touting Jeuneau's "proprietary" manufacturing process. (*Id.* ¶ 9) The Amended Complaint asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Securities and Exchange Commission ("SEC") Rule 10b-5 in connection with Defendants' public statements during the Class Period. The Amended Complaint also asserts an insider trading claim against Defendant Alphaeon under Section 20A of the Exchange Act in connection with Alphaeon's sale of Evolus shares on May 20, 2019. (*Id.* ¶¶ 255, 264, 270, 283)

Defendants have moved to dismiss the Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). (Dkt. Nos. 100, 103) Defendants argue that Plaintiffs' Section 10(b) claim should be dismissed for failure to plead facts establishing either (1) false or misleading statements; or (2) a strong inference of scienter. (Evolus Br. (Dkt. No. 102) at 19-36; Alphaeon Br. (Dkt. No. 104) at 13-22)² Defendants further contend that Plaintiffs' Section 20(a) claims should be dismissed for failure to plead a primary violation of the Exchange Act. (Evolus Br. (Dkt. No. 102) at 37; Alphaeon Br. (Dkt. No. 104) at 21-22) Defendant Alphaeon separately argues that the Section 20A insider trading claim should be dismissed for failure to plead facts

¹ In its briefing, Alphaeon states that it "changed its name to AEON Biopharma, Inc. on December 19, 2019." (Alphaeon Br. (Dkt. No. 104) at 7 n.1) Because the Amended Complaint and several of Evolus's securities filings refer to the company as Alphaeon, this Court will use that name in this opinion.

² The page numbers of documents referenced in this opinion correspond to the page numbers designated by this District's Electronic Case Files ("ECF") system.

demonstrating that Alphaeon possessed material non-public information when it made the relevant trades. (Id. at 26-28)

For the reasons stated below, Defendants’ motions to dismiss will be granted.

BACKGROUND

I. FACTS³

A. The Parties

Lead Plaintiff Raja Ahmad and named Plaintiffs Kim Keller, Mitchel Sisun, and Peter Diaferia all purchased Evolus common stock during the Class Period. (Am. Cmplt. (Dkt. No. 70) ¶¶ 28-31)

Defendant Evolus is a Delaware corporation with its principal place of business in Newport Beach, California. (Id. ¶ 32) Evolus common stock trades on the NASDAQ stock exchange under the symbol “EOLS.” (Id.)

Defendant David Moatazedi has been Evolus’s chief executive officer (“CEO”) since May 2018. (Id. ¶ 33) Defendant Rui Avelar has been Evolus’s chief medical officer and head of Research and Development since January 2014. (Id. ¶ 34) Defendant Lauren Silvernail

³ The Court’s factual statement is drawn from the Amended Complaint. In deciding a motion to dismiss in the securities fraud context, courts “consider [the complaint,] any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit.” ATSI Commc’ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007). “Because the Amended Complaint quotes and relies upon statements made during . . . analyst calls . . . , the Court may properly consider the full transcripts of those calls . . . in connection with the Rule 12(b)(6) motion without converting it to one for summary judgment.” Fort Worth Employers’ Ret. Fund v. Biovail Corp., 615 F. Supp. 2d 218, 232 n.3 (S.D.N.Y. 2009). Where the documents on which the Amended Complaint relies “contradict the allegations of the . . . complaint, the documents control.” In re Elan Corp. Sec. Litigations, 543 F. Supp. 2d 187, 206 (S.D.N.Y. 2008) (internal quotation marks and citation omitted).

has been Evolus’s chief financial officer (“CFO”) and Executive Vice President since May 2018. (Id. ¶ 35)⁴

Defendant Alphaeon is a Delaware corporation with its principal place of business in Irvine, California. (Id. ¶ 36) Alphaeon is a “technology company focused on providing healthcare products and services.” Alphaeon “own[ed] 56% of [Evolus’s] outstanding shares of common stock” at the beginning of the Class Period. (Id.) Evolus has referred to Alphaeon as its “parent company” in SEC filings. (Id.)

B. Pre-Class Period Events

1. The Development of BTX Products by Allergan and Medytox

“Botulinum Neurotoxin” or “BTX” is a “product made from C. botulinum, the bacteria that causes botulism.” (Id. ¶ 46) BTX products are “biologics” with “therapeutic and aesthetic applications,” such as being used to “temporarily improve the appearance of glabellar lines (i.e. frown lines), crow’s feet and forehead lines.” (Id.)

Allergan was “the first company to launch a BTX product in the United States,” and “received [U.S. Food and Drug Administration] approval for its trademark product BOTOX for therapeutic uses in 1989 and for aesthetic uses in 2002.” (Id. ¶ 47) Medytox is a “South Korean company founded in 2000 for the purpose of researching, developing and manufacturing BTX products.” (Id. ¶ 48) In 2006, Medytox “received approval [from] the Korean Ministry of Food and Drug Safety to sell the first BTX product developed in Korea called Meditoxin.” (Id.)

In September 2013, Allergan and Medytox “entered into a licensing and supply agreement whereby Medytox licensed a formulation of its BTX product to Allergan for

⁴ In this opinion, the Court refers to Moatazedi, Avelar, and Silvernail collectively as the “Individual Defendants.”

commercialization in the U.S.” (Id. ¶ 49) Allergan became the “exclusive licensee of Medytox’s BTX product.” (Id.)

2. Evolus’s Development of Jeuveau

Evolus is a “medical aesthetics company established in 2012.” Its “only product” is Jeuveau, “a purified BTX product for the temporary improvement in the appearance of moderate to severe frown lines in adults.” (Id. ¶ 50) From its inception, “Evolus’s sole focus has been bringing Jeuveau to the U.S. market.” (Id.)

In January 2013, Medytox and Evolus “began negotiating a supply and license agreement whereby Medytox would sell and supply its BTX product, Meditoxin, to Evolus so that Evolus could sell it in the United States.” (Id. ¶ 53)

However, on September 20, 2013, Evolus entered into an agreement with another South Korean pharmaceutical company, Daewoong, pursuant to which

Daewoong would manufacture and supply Jeuveau to Evolus and grant Evolus an exclusive license to import, distribute, promote, market, develop, offer for sale or otherwise commercialize and exploit Jeuveau in the U.S., EU, Canada, Australia, Russia and South Africa (and a non-exclusive license to do so in Japan).

(Id. ¶ 54) DWP-450 is Daewoong’s internal designation for its BTX product. (Id. ¶¶ 55) At the time, “[a]nalysts estimated that the value of the agreement between Evolus and Daewoong was approximately \$250 million.” (Id. ¶ 56)

In early 2014, Evolus “began the process of seeking FDA approval to market Jeuveau in the U.S.” (Id. ¶ 57) Evolus also began “conduct[ing] . . . clinical trials of Jeuveau” in the United States. (Id. ¶ 58) At this same time, Defendant Rui Avelar “left his position as Chief Medical Officer at Allergan to become the Chief Medical Officer of Evolus.” (Id. ¶ 60) Before joining Evolus, Avelar had served as Allergan’s chief medical officer for “almost ten years.” (Id. ¶ 34)

3. **Medytox Files Misappropriation Lawsuits in California and South Korea**

On June 6, 2017, Medytox filed a lawsuit against Evolus, Daewoong, and a former Medytox employee, Byung Kook (“BK”) Lee, in the Superior Court of California, alleging that “Jeuveau had been misappropriated from Medytox when . . . BK Lee . . . stole both Medytox’s proprietary BTX strain and Medytox’s proprietary manufacturing process for its BTX strain and gave them to Daewoong in exchange for employment at Daewoong, compensation and other favors.” (Id. ¶¶ 6, 110) Medytox “sought to enjoin Evolus from distributing Jeuveau in the U.S.” (Id. ¶ 27)

The Amended Complaint alleges that both Jeuveau and Medytox’s BTX strains are developed from a particular strain of C. botulinum known as the “Hall A-hyper strain,” which was first developed by U.S. Army researchers in the 1940s. (Id. ¶¶ 83-84) In litigation, Daewoong has claimed that its BTX strain is a Hall A-hyper strain and that it discovered the BTX strain “in the soil in South Korea.” (Id. ¶ 6) The Amended Complaint alleges that Daewoong’s account of this discovery is impossible, because the Hall A-hyper strain “cannot be isolated from nature because it does not contain spores.” (Id. ¶ 84) That is, “without spores, the Hall strain cannot be isolated from soil,” as Daewoong has claimed. (Id.)

On June 19, 2017, Evolus announced that the U.S. Food and Drug Administration (“FDA”) had accepted its Biologics License Application (“BLA”) for Jeuveau. (Id. ¶ 61)

On October 12, 2017, the California court “dismissed BK Lee from the suit for lack of personal jurisdiction and dismissed Daewoong based on forum non conveniens.” (Id. ¶ 110) On October 30, 2017, Medytox filed a lawsuit in South Korea alleging that “Daewoong [had] misappropriated trade secrets BK Lee stole from it.” (Id. ¶ 109) The California court “stayed the case as to Evolus pending the outcome of the Korea Action.” (Id. ¶ 110)

In December 2017, Medytox filed a Citizen Petition with the FDA

seeking to delay approval of the BLA for Jeuveau until the FDA determines the identity and source of the botulinum strain for Jeuveau. The Citizen Petition alleged among other things, that Evolus made false statements in its BLA for Jeuveau about the source and identity of the BTX strain for Jeuveau. The Citizen Petition requested that the FDA require Evolus's BLA to include what is . . . called a SNP (single nucleotide polymorphism) analysis of the genome sequence for Jeuveau's BTX strain.

(Id. ¶ 111) The FDA “declined to delay approval of Jeuveau despite the Citizen Petition.” (Id.)

4. Evolus Becomes a Public Company, and Moatzedi and Silvernail Join Evolus

In February 2018, Evolus completed an initial public offering and began trading on the NASDAQ stock exchange. (Id. ¶ 52)

On May 7, 2018, Defendant Moatazedi left his position as the senior vice president of U.S. Medical Aesthetics at Allergan to become the chief executive officer of Evolus.

(Id. ¶ 62) Before joining Evolus, Moatazedi

spent 14 years at Allergan, in his words, “all in medical aesthetics in the same category [and] worked on brands like BOTOX, launched the Juvederm franchise back in 2006 and held different roles and responsibilities over that time, including running the U.S. Aesthetics business.”

In confidential testimony in the ITC Litigation [initiated by Allergan and Medytox in 2019,] Moatazedi admitted that as recently as early . . . 2018 he was “the most senior person in [Allergan] with direct responsibility for BOTOX Cosmetic” and was thus “privy to all strategic thinking and planning . . . with regard to the commercial side of BOTOX Cosmetic.”

One of the last things Moatazedi did at Allergan was assess the competitive threat Evolus posed to BOTOX.

(Id. ¶¶ 62-64) (citation omitted)

Defendant Silvernail joined Evolus as the company's chief financial officer in May 2018 after “work[ing] for eight years at Allergan as a Vice President of Business Development.” (Id. ¶ 35)

5. The Confidential Witness Joins Evolus

In October 2018, an individual identified in the Amended Complaint as “Confidential Witness 1” (“CW1”) began working at Evolus as the director of medical affairs.

(Id. ¶ 122) CW1 reported to Defendant Avelar, and CW1’s role was

to provide the Company with unbiased education about the pharmaceutical products it markets. As Executive Director, Medical Affairs[,] at Evolus CW1 attended tradeshows, conducted training on Jevueau for clinicians using Jevueau, responded to inquiries from doctors about the product, reviewed marketing materials the Company authored[,] and hosted clinical discussions with doctors in which he presented scientific data concerning Jevueau.

(Id.)

The Amended Complaint further alleges that

CW1 stated with certainty that [Evolus] did not investigate the allegations that Jevueau was the product of misappropriation. CW1 stated that the Company had no interest in investigating the incredible claim that Jevueau was discovered in the soil in Korea because it would not be beneficial for Evolus to know that Jevueau was misappropriated.

Given CW1’s high-level position in the Company and his daily interactions with the Individuals Defendants[,] CW1 was in a position to know whether or not Defendants had conducted an investigation into the allegations that Jevueau was the product of misappropriation. CW1 is certain that they did not.

(Id. ¶¶ 126-27)

CW1 left Evolus “half-way through his tenure at Evolus” because

he realized that the position was not a good fit primarily because of the difficulties he encountered with Defendant Avelar. CW1 explained that . . . Defendant Avelar was not transparent. For example, Avelar failed to inform CW1 about a clinical study the Company performed in Korea until the results of the study were published, despite th[e] fact that a company’s Director of Medical Affairs should always be apprised of all clinical trials.

(Id. ¶ 123)

6. The January 2019 ITC Complaint

On January 25, 2019, Allergan and Medytox filed a complaint with the U.S. International Trade Commission⁵ raising allegations of misappropriation similar to those made in the 2017 California and South Korea lawsuits. (*Id.* ¶ 102) The ITC Complaint alleges that former Medytox employee BK Lee misappropriated trade secrets belonging to Medytox and provided them to Daewoong in exchange for employment and compensation. Daewoong then used those trade secrets to develop DWP-450, Daewoong's internal designation for the BTX product marketed in the United States as Jueveau. (Am. Cmplt. Ex. A (ITC Cmplt.) (Dkt. No. 70-1) ¶¶ 1, 15) The ITC Complaint alleges that two trade secrets belonging to Medytox were misappropriated: (1) Medytox's manufacturing process for its BTX strain; and (2) the BTX strain itself. (*Id.* ¶ 52)

As evidence of the misappropriation, the ITC Complaint alleges the following:

- a. Medytox's electronic records clearly demonstrate that BK Lee stole its confidential manufacturing information, and there is strong circumstantial evidence that he also stole a physical sample of its BTX strain itself.
- b. After leaving Medytox in August 2008, BK Lee began consulting for Daewoong from at least 2010 to 2011, the same time Daewoong was developing DWP-450.
- c. Daewoong made payments to BK Lee under circumstances that do not appear to correspond to the consulting services that he purportedly provided to Daewoong.
- d. The timeline of Daewoong's development of DWP-450 was implausibly short: Without any staff experienced in the development of BTX products, Daewoong claimed to identify its own BTX strain in a matter of weeks from roughly 200 soil

⁵ The ITC "is an independent, quasi-judicial administrative agency . . . responsible for, among other things, adjudicating allegations of unfair competition and unfair acts in the importation of articles into the United States." (*Id.* ¶ 92) The ITC "has authority to investigate infringement of U.S. patent and trade secret rights by products imported in the United States." (*Id.*)

samples and then applied to begin clinical trials on its own BTX product less than two years later.

e. The origin story Daewoong has told (that it discovered a non-sporulating, Hall - A BTX strain in the soil) is scientifically impossible.

f. Daewoong has repeatedly resisted any testing of its BTX strain or disclosure of gene sequencing information that would resolve whether the strain from which DWP-450 is developed is the same as Medytox's strain

(Id. ¶ 91)

The ITC Complaint requests, inter alia, “cease and desist orders” preventing Evolus from importing Jeuveau into the United States and marketing Jeuveau in the United States. (Id. at 65)

C. Events During the Class Period: February 1, 2019 to July 6, 2020

1. The FDA Approves Jeuveau for Marketing in the United States

On February 1, 2019 – the first day of the Class Period – Evolus issued a press release “announc[ing] that it [had] received FDA approval to market Jeuveau.” (Id. ¶ 67) The press release describes Jeuveau as a “proprietary 900 [kilodalton, or kDa,] purified botulinum toxin type A formulation” that is “indicated for the temporary improvement in the appearance of moderate to severe glabellar lines in adults.” (Rosenberg Decl., Ex. A (Feb. 1, 2019 Evolus press release) (Dkt. No. 102-1) at 2) Evolus also described Jeuveau as a “proprietary” BTX product in subsequent press releases, securities filings, and other public statements issued during the Class Period between February 4, 2019 and May 11, 2020. (Am. Cmpl. (Dkt. No. 70) ¶¶ 177, 186, 190, 194, 196, 202, 205, 211, 225)

In a February 4, 2019 article, the pharmaceutical news website StatNews described the ITC Complaint and Evolus's reaction to it:

“An Evolus spokesman wrote us that the claims are ‘completely without merit’ and the timing reflects the ‘competitive threat (Jeuveau) presents to the Botox franchise. This represents another legal maneuver in a long litany of attempts by

Allergan and Medytox to stifle competition and limit physician and consumer choice . . . Given this history, we have been prepared and will vigorously defend our intellectual property.”

(Id. ¶ 180) (emphasis omitted)

2. The ITC Begins Investigating the Misappropriation Claim

On March 1, 2019, the ITC “announced [that] it had agreed to initiate an investigation and instituted the ITC Litigation under ITC Inv. No. 337-TA-1145, In the Matter of Certain Botulinum Toxin Products.” (Id. ¶ 112)

In a March 4, 2019 article, StatNews announced the ITC action and reported that

“an Evolus spokeswoman wrote to say ‘we remain confident in our intellectual property and proprietary manufacturing process and will work with the ITC through its review. We continue to believe that Allergan and Medytox’s claims are completely without merit and that their complaint and associated timing reflect their level of concern[] surrounding Evolus’ entry as a new competitor that will enhance consumer and physician choice.’”

(Id. ¶ 184) (emphasis omitted)

On March 5, 2019, the ITC issued a protective order “governing confidential business information produced or exchanged in the [ITC’s] [i]nvestigation.” (Id. ¶ 113) The protective order defines “[c]onfidential business information” as

information which has not been made public and which concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, the disclosure of which information is likely to have the effect of either (i) impairing the Commission’s ability to obtain such information as is necessary to perform its statutory functions; or (ii) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information.

(Rosenberg Decl., Ex. P (Mar. 5, 2019 ITC Prot. Order) (Dkt. No. 102-16) ¶ 1)

The protective order restricts the disclosure of materials designated as “confidential business information” to the following:

(i) outside counsel for parties to this investigation, including necessary secretarial and support personnel assisting such counsel; (ii) qualified persons taking testimony involving such documents or information and necessary stenographic and clerical personnel thereof; (iii) technical experts and their staff who are employed for the purposes of this litigation (unless they are otherwise employed by, consultants to, or otherwise affiliated with a non-governmental party, or are employees of any domestic or foreign manufacturer, wholesaler, retailer, or distributor of certain botulinum toxin products, processes for manufacturing or relating to same and certain products containing same, which are the subject of this investigation); (iv) the Commission, the administrative law judge, the Commission staff, and personnel of any governmental agency as authorized by the Commission; and (v) the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; and (vi) U.S. government employees and contract personnel, solely for cybersecurity purposes.

(Id. ¶ 3)

3. Defendants’ Stock Sales in May and June 2019

Between May 17, 2019 and June 3, 2019, Defendant Alphaeon sold 6,606,518 shares of Evolus stock at a price of \$19.25 per share for net proceeds of \$127,175,471. (Id. ¶ 228)

On May 31, 2019, Defendant Lauren Silvernail sold 2,612 shares of Evolus stock at \$13.53 per share, for proceeds of \$35,340.36. (Id.)

4. Developments in the ITC Investigation and Defendants’ Stock Transactions

In connection with fact discovery in the ITC investigation, the ITC Court ordered Medytox and Allergan to produce the allegedly misappropriated trade secrets, *i.e.*, the BTX strain used to manufacture the BTX product they alleged Daewoong and Evolus had misappropriated as well as the manufacturing process for the product. . . .

(Id. ¶ 195) Fact discovery in the ITC investigation closed on July 19, 2019. (Id. ¶ 114)

On August 12, 2019, Defendant Moatazedi participated in an earnings call in connection with Evolus’s announcement of its financial results for the second quarter of 2019.

(Id. ¶ 199) In response to an analyst’s question about the ITC case, Moatazedi stated:

I know there’s a lot of interest around the legal case. Look, we’re not going to be in a position to comment about the specifics as the case continues to unfold. As we’ve said from the beginning, we remain very confident in our IP, and we’ll let the court system continue to work through the case.

(Rosenberg Decl., Ex. K (Aug. 12, 2019 earnings call transcript) (Dkt. No. 102-11) at 16)

Expert discovery in the ITC investigation closed on October 30, 2019. (Id. ¶ 114)

On November 6, 2019, Evolus “conducted a public offering of 5,217,000 shares of common stock at a price of \$13.00 per share, providing Evolus net proceeds from the November Offering of approximately \$63.5 million.” (Id. ¶ 17)

On January 7, 2020, Defendant Rui Avelar sold 39,442 shares of Evolus stock for proceeds of \$442,423.82. (Id. ¶ 228)

5. The ITC Evidentiary Hearing

Between February 4, 2019 and February 7, 2019, an ITC administrative law judge (“ALJ”) conducted an evidentiary hearing concerning the misappropriation allegations. (Id. ¶ 116) Evolus’s general counsel, Jeff Plumer, attended portions of the hearing, along with outside counsel for Evolus, Daewoong, Medytox, and Allergan. (Id.)

The transcript for the evidentiary hearing indicates that the proceedings included “open” sessions attended by all interested parties, and “confidential” sessions that involved confidential business information (“CBI”), which were attended solely by outside counsel. For example, after Medytox’s lawyer announced that the parties’ opening statements would “go through CBI . . . of all parties,” he requested that the ALJ “ask the parties themselves to exit the courtroom and leav[e] only those counsel who are able to hear CBI of all parties.” (Rosenberg

Decl., Ex. V (Feb. 4, 2020 ITC Hrg. Tr.) (Dkt. No. 102-22) at 11) The ALJ then asked the “corporate people” to leave and stated that the hearing would “go [forward] on the confidential record.” (Id.)

The first witness at the hearing was Allergan and Medytox’s expert witness, Dr. Paul Keim, a “college professor and . . . the director of the Institute of Genomics and Microbiology” in the United States. (Id. at 13-14) Allergan and Medytox retained Dr. Keim to offer a scientific opinion about the relationship between Medytox’s BTX strain and Daewoong’s BTX strain. (Id. at 17) Dr. Keim testified that, based on his analysis, “the Daewoong strain came from or was derived from the Medytox strain.” (Id. at 18) Dr. Keim offered his overall conclusion about the origins of the Daewoong strain in an “open” session, and the proceedings then became “confidential.” (Id.)

6. Defendants’ Public Statements After the ITC Evidentiary Hearing

On February 25, 2020, Defendant Moatazedi participated in an earnings call to discuss Evolus’s financial results for the fourth quarter of 2019. (Am. Cmplt. (Dkt. No. 70) ¶ 118) During the earnings call, he provided the following update concerning the ITC investigation:

As you may know, the ITC hearings took place February 4th through the 7th in Washington D.C. In June, the judge will reach an initial determination, followed by a final decision by the ITC targeted for October 2020. In the interim, it’s customary for various redacted versions of motions, briefs and transcripts to become public. However, I would caution you not to draw any definite conclusions from individual documents, as the initial determination will be decided based on the totality of the merits as assessed by the judge in June and the ITC in October. We look forward to resolving the case before year end and remain confident in the strength of our IP. We can’t speak further to this matter on today’s call, but recognize it is something important to all of our employees and to our shareholders. . . .

So, let me start with the ITC. Clearly top of mind for investors as we mentioned earlier, the hearing took place earlier in February. And with the ITC, the majority of those hearings are confidential. It’s not like a public trial where most of the

information is available to you. So unfortunately, . . . I'm not able to provide any more color than what I provided earlier. That being said, nothing changed through the case. We feel confident in the strength of our IP and we expect that this case will be resolved before the end of the year and this will be behind us.

(Rosenberg Decl., Ex. I (Feb. 25, 2020 earnings call transcript) (Dkt. No. 102-9) at 10, 14)

In a March 4, 2020 press release, Medytox stated that

during the ITC Hearing the ITC Staff Attorney sided with the allegations that Evolus and Daewoong misappropriated Medytox's trade secret BTX strain. Medytox commented that "ITC attorneys' opinions are known to have a profound effect on the final decision of the court."

(Am. Cmplt. (Dkt. No. 70) ¶ 216)

That same day, Evolus issued a press release stating the following:

In several media reports this week, Medytox has made comments on the International Trade Commission (ITC) case, which Evolus believes are speculative and intended to create confusion in the U.S. market ahead of the ITC Judge's initial determination in June 2020 and the ITC's final determination, which is targeted for October 2020.

Importantly, nothing has changed as a result of the media reports from Korea. The ITC Judge will make his own independent decision based upon all the evidence presented at the hearing and through all the parties' filings. The Judge assigned to the ITC is not obligated to accept a staff attorney's position on the facts, and it's fairly common for the Judge and the staff attorney to disagree on substantive matters.

Evolus and Daewoong remain confident in the strength of our intellectual property and will continue to vigorously defend it through the entirety of the ITC process.

(Id. ¶ 217) (emphasis omitted) Later that day, securities analysts at Cantor Fitzgerald issued a report citing "conversations with [Evolus] management this morning." The analysts reported that their "key takeaway is that nothing has changed as a result of Korean media reports." (Id. ¶ 219)

On March 11, 2020, at a global healthcare conference, Defendant Silvernail made the following remarks concerning the status of the ITC investigation:

I think if you look through it all and you look through all the information that is out there, it's very contradictory. And so I'd be careful about drawing any conclusions about who sided with whom on what. There just is a tremendous amount of information coming out and will come out over the next 90 days or so. And we believe in the merits of our case, we're confident in our IP. But it's hard to comment on each individual fact that's going to come out. Some of them are going to look like the case is swinging to Daewoong and some are going to make it look like it's swinging to Medytox. . . .

As I mentioned earlier, when you look at the case, there will be a preliminary decision in June and a final decision in October. If there is a settlement, it will be between Medytox and Daewoong. And only they can really comment on that, and so we won't be commenting on settlement today at all. For us, we have – we are in a very solid position. We like our odds in this. We believe in the merits of our case and are very confident in the IP. So we are not really worried about the outcome here.

(Id. ¶¶ 221, 223)

7. The ITC ALJ Issues the Final Initial Determination

On July 6, 2020 – the last day of the Class Period – the ITC ALJ issued his Final Initial Determination. The ALJ determined that Daewoong had misappropriated trade secrets from Medytox in connection with the development of the BTX strain that Daewoong had licensed to Evolus. (Id. ¶ 232) The ITC ALJ recommended “a limited exclusion order preventing Evolus from importing Jeuveau into the U.S. for ten years and a cease-and-desist order that would prevent Evolus from marketing and selling Jeuveau in the U.S., also for a period of ten years.” (Id.)

Evolus's shares “dropped to \$3.35 per share over the next two trading days, representing a decline of 37%, damaging investors.” (Id. ¶ 233)

D. Post-Class Period Events

1. The Final Initial Determination

On August 6, 2020, the ITC issued a 282-page public version of the ALJ's Final Initial Determination. In this version of the FID, the ALJ explains the reasoning for his decision.

The portions of the FID discussing confidential business information are redacted. (Am. Cmplt., Ex. B (July 6, 2020 FID, Public Version) (Dkt. No. 70-2))

As set forth in the FID, the ITC investigation presented several disputed issues.

As an initial matter, the parties disputed whether Daewoong had, in fact, misappropriated Medytox's proprietary information concerning its BTX strain and manufacturing process. As for the alleged theft of Medytox's BTX strain, the ALJ concluded that "it has not been established that Dr. BK Lee took the strain from Medytox and, for consideration or otherwise, gave it to Daewoong." (*Id.* at 100) The ALJ concluded, however, that "misappropriation has been shown through . . . genetic evidence," because the Medytox and Daewoong BTX strains

share distinctive DNA fingerprints, six [single nucleotide polymorphisms ('SNPs')], that confirm they are a match. [Allergan's and Medytox's expert witness] Dr. Keim identified six SNPs shared by the Medytox and Daewoong BTX strains that are unique to those two strains and distinguishes them from all other known sequenced *C. botulinum* strains. Moreover, these six SNPs do not exist in the Hall A[-]hyper strain from which the Medytox BTX strain is derived. The possibility of two unrelated strains sharing the same six identical SNPs at the exact same nucleotide positions along a DNA sequence of nearly 3.7 million nucleotides is effectively impossible.

Respondents' expert, Dr. Sherman, initially asserted that Dr. Keim's analysis of the Daewoong and Medytox sequences was erroneous, because Dr. Keim only found 21 SNPs between the Daewoong and Medytox genomes. The real number, Dr. Sherman asserted, was 145 SNPs and 21 insertions and deletions ("indels," for insertions and deletions) – for a total of 166 – between the Medytox and Daewoong genomes. However, after Dr. Keim served his review of Dr. Sherman's analysis, Dr. Sherman had to agree with Dr. Keim at least in part regarding the identification of false positive SNPs in Dr. Sherman's earlier analysis. Dr. Sherman now states there are a total of only 28 SNPs and indels between the Medytox and Daewoong genomes, not his original identification of 166 SNPs and indels. Dr. Sherman essentially admits that 138 out of 166 SNPs and indels that he initially identified were erroneous. The evidence demonstrates Dr. Keim's analysis to be more reliable.

The evidence relating to six particular single nucleotide polymorphisms or SNPs establishes that the Daewoong strain is derived from the Medytox strain.

(*Id.* at 101, 106-07) (citations and footnote omitted)

As to the alleged misappropriation of Medytox’s manufacturing process for its BTX strain, the ALJ concluded that “the record is not clear” that “Dr. BK Lee . . . divulged trade secret information to Daewoong.” (*Id.* at 139) The ALJ nonetheless concluded that Daewoong had “misappropriated the manufacturing process from Medytox,” citing the following “three factors”: “(1) the similarity of Daewoong’s process to Medytox’s; (2) the lack of evidence of Daewoong’s independent development; and (3) the implausibly fast timeline by which Daewoong achieved BTX production at commercial scale.” (*Id.*)

The parties also disputed whether Medytox’s BTX strain and manufacturing process constitute protectable trade secrets. The ALJ concluded that both the BTX strain itself and Medytox’s manufacturing process constitute protectable trade secrets. (*Id.* at 69-99, 120-134)

Evolus and Daewoong also disputed whether (1) the ITC had subject matter jurisdiction under 19 U.S.C. § 1337 (*id.* at 29-35); (2) Medytox and Allergan had standing (*id.* at 35-45); (3) Allergan could establish the existence of a domestic industry under 19 U.S.C. § 1337 (*id.* at 159-197); and (4) Allergan could show that its domestic industry was being substantially injured. (*Id.* at 197-232). The ALJ ruled in favor of Allergan and Medytox on each issue.

Finally, Evolus and Daewoong raised affirmative defenses of statute of limitations (*id.* at 232-242), laches (*id.* at 242-250), and unclean hands (*id.* at 250-257), all of which the ALJ rejected.

2. The ITC’s Final Determination

On December 16, 2020, the ITC issued its Final Determination. The ITC affirmed the FID in part, reversed it in part, and reduced the importation ban and cease-and-desist order from a period of ten years to twenty-one months. (Am. Cmplt. (Dkt. No. 70) ¶¶ 235-36)

On January 13, 2021, the ITC issued a public version of its opinion explaining the basis for its December 16, 2020 Final Determination. (Rosenberg Decl., Ex. W (Dec. 16, 2020 FD Opinion) (Dkt. No. 102-23)) While the ITC affirmed most of the ALJ’s findings in the FID – including that Daewoong had misappropriated Medytox’s BTX strain and its manufacturing process, and that Medytox’s manufacturing process constitutes a protectable trade secret – the ITC reversed the ALJ’s finding that Medytox’s BTX strain constitutes a protectable trade secret. According to the ITC, Medytox’s BTX strain is not protectable, because it

was circulated without restrictions, and because . . . there is no evidence in the record that the Medytox strain is distinct from the parent strain given to Medytox.

(Id. at 9-13)

Because Medytox’s BTX strain does not constitute a protectable trade secret, the ITC found that Allergan and Medytox “cannot establish the unfair act of trade secret misappropriation by Daewoong as to the Medytox strain.” (Id. at 9) The ITC went to find that when “the misappropriation of the Medytox manufacturing process is considered independently,” the proper duration of the importation ban and cease-and-desist order is twenty-one months. (Id. at 15-16)

II. PROCEDURAL HISTORY

On October 16, 2020, the first of two putative securities fraud class actions was filed on behalf of investors who held Evolus common stock during the Class Period. (Dkt. No. 1) On November 13, 2020, this Court consolidated the two actions. (Dkt. No. 12)

On September 17, 2021, this Court appointed Lead Plaintiff and Lead Counsel. (Dkt. No. 64)

Lead Plaintiff filed the Amended Complaint on October 4, 2021. (Dkt. No. 70)

Evolus and the Individual Defendants moved to dismiss the Amended Complaint pursuant to Rule 9(b), Rule 12(b)(6), and the PSLRA on January 18, 2022. (Dkt. No. 100) Defendant Alphaeon moved to dismiss the Amended Complaint on February 10, 2022. (Dkt. No. 103) Lead Plaintiff filed opposition briefs as to both motions on April 20, 2022 (Dkt. Nos. 108, 110), and Defendants filed reply briefs on June 16, 2022. (Dkt. Nos. 106, 111)

DISCUSSION

I. RULE 12(b)(6) STANDARD

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 554, 570 (2007)). “In considering a motion to dismiss . . . the court is to accept as true all facts alleged in the complaint,” Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir. 2007) (citing Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 87 (2d Cir. 2002)), and must “draw all reasonable inferences in favor of the plaintiff.” Id. (citing Fernandez v. Chetoff, 471 F.3d 45, 51 (2d Cir. 2006)).

A complaint is inadequately pled “if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement,’” Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 557), and does not provide factual allegations sufficient “to give the defendant fair notice of what the claim is and the grounds upon which it rests.” Port Dock & Stone Corp. v. Oldcastle N.E., Inc., 507 F.3d 117, 121 (2d Cir. 2007) (citing Twombly, 550 U.S. at 555). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” to establish entitlement to relief. Iqbal, 556 U.S. at 678.

II. SECTION 10(b) CLAIM

A. Legal Standards

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful “for any person, directly or indirectly . . . [t]o use or employ, in connection with the purchase or sale of any security, . . . any manipulative or deceptive device or contrivance” in violation of the rules set forth by the SEC for the protection of investors. 15 U.S.C. § 78j. Pursuant to SEC Rule 10b–5, promulgated thereunder, it is unlawful:

- (a) To employ any device, scheme, or artifice to defraud,
- (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
- (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To plead a material misstatement or omission claim under Section 10(b) and Rule 10b-5, a plaintiff must “allege that the defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff’s reliance was the proximate cause of its injury.” ATSI Commc’ns, 493 F.3d at 105 (citing Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005)).

“‘A complaint alleging securities fraud pursuant to Section 10(b) of the Securities Exchange Act is subject to two heightened pleading standards.’” In re Cannavest Corp. Sec. Litis., 307 F. Supp. 3d 222, 236 (S.D.N.Y. 2018) (quoting In re Gen. Elec. Co. Sec. Litigations, 857 F. Supp. 2d 367, 383 (S.D.N.Y. 2012)). “First, the complaint must satisfy Federal Rule of Civil Procedure 9(b), which requires that the complaint ‘state with particularity the

circumstances constituting fraud.” Id. (quoting Fed. R. Civ. P. 9(b)). This requirement “serves to provide a defendant with fair notice of a plaintiff’s claim, safeguard his reputation from improvident charges of wrongdoing, and protect him against strike suits.” ATSI Commc’ns, 493 F.3d at 99. Accordingly, a securities fraud complaint based on misstatements must “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” Rombach v. Chang, 355 F.3d 164, 170 (2d Cir. 2004) (quoting Mills v. Polar Molecular Corp., 12 F.3d 1170, 1175 (2d Cir. 1993)).

A securities fraud complaint must also meet the pleading requirements of the PSLRA, 15 U.S.C. § 78u-4(b). The PSLRA requires a plaintiff to “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A); see also Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 313 (2007) (“The PSLRA requires plaintiffs to state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant’s intention to ‘deceive, manipulate, or defraud.’” (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 194 & n.12 (1976))). “To qualify as ‘strong’ within the intendment of [the PLSRA][,] . . . an inference of scienter must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” Tellabs, 551 U.S. at 314; see also id. (“[T]o determine whether a complaint’s scienter allegations can survive threshold inspection for sufficiency, a court governed by [the PLSRA] must engage in a comparative evaluation; it must consider, not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged.”). “A complaint will survive . . . only if a

reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” Id. at 324.

B. Alleged Fraudulent Statements

The Amended Complaint alleges that, during the Class Period, Defendants made false and misleading statements (1) expressing confidence in Evolus’s legal position in the ITC litigation (id. ¶¶ 180, 184, 199-200, 212, 213, 217, 219, 221, 223, 225); (2) describing Jeuveau as Evolus’s “proprietary” BTX product (id. ¶¶ 173, 177, 186, 190, 194, 196, 202, 205, 211, 225); (3) concerning the “competitive strengths” of Jeuveau, while omitting the fact that Jeuveau was the result of misappropriation (id. ¶¶ 186, 194, 209-10); and (4) asserting that the “original founder” of Evolus had “developed” Jeuveau. (Id. ¶ 188)

Defendants respond that the statements cited by Plaintiffs are not actionably false or misleading. (Evolus Br. (Dkt. No. 101) at 19, 36)

1. Statements Concerning Likelihood of Success in the ITC Litigation

Plaintiffs contend that Defendants’ statements concerning Evolus’s likelihood of success in the ITC litigation were false and misleading. In this regard, Plaintiffs cite Defendants’ assertion that the claims in the ITC litigation were “completely without merit” (Am. Cmplt. (Dkt. No. 102) ¶¶ 180, 184); that the Company “remain[ed] confident in [its] intellectual property” (id. ¶¶ 184, 199-200, 212-13, 217, 221, 223, 225); that “nothing changed” as a result of the ITC evidentiary hearing in February 2020 (id. ¶¶ 213, 217, 219); and that Evolus “believe[ed] in the merits of [its] case.” (Id. ¶¶ 221, 223)

According to Plaintiffs, these statements were false and misleading, because (1) Daewoong had misappropriated Medytox’s BTX strain and its manufacturing process; and (2) as a result, Defendants “had no reasonable basis to believe” that Evolus would prevail before the ITC. (Id. ¶¶ 181, 185, 201, 214, 218, 220, 222, 224, 226)

Defendants counter that the statements cited by Plaintiffs are non-actionable opinions, forward-looking statements, or puffery, and that in certain instances Defendants did not make the statements cited by Plaintiffs. (Def. Br. (Dkt. No. 101) at 19-26, 36)

a. Statements by Unidentified Speakers

The Amended Complaint challenges three statements about the ITC litigation that were disseminated in online news articles and in an analyst report and that were attributed to unnamed Evolus insiders:

- From a February 4, 2019 StatNews article: “An Evolus spokesman wrote us that the claims are ‘completely without merit’ and the timing reflects the ‘competitive threat (Jeuneau) presents to the Botox franchise. This represents another legal maneuver in a long litany of attempts by Allergan and Medytox to stifle competition and limit physician and consumer choice . . . Given this history, we have been prepared and will vigorously defend our intellectual property.’” (Am. Cmplt. (Dkt. No. 70) ¶ 180) (emphasis omitted)
- From a March 4, 2019 StatNews article: “[A]n Evolus spokeswoman wrote to say ‘we remain confident in our intellectual property and proprietary manufacturing process and will work with the ITC through its review. We continue to believe that Allergan and Medytox’s claims are completely without merit and that their complaint and associated timing reflect their level of concern surrounding Evolus’ entry as a new competitor that will enhance consumer and physician choice.’” (Id. ¶ 184) (emphasis omitted)
- In a March 4, 2020 analyst report, Cantor Fitzgerald cited “conversations with [Evolus] management” in stating that its “key takeaway is that nothing has changed as a result of Korean media reports [concerning Medytox’s account of proceedings before the ITC ALJ]. The judge will make the Initial Determination based on the totality of evidence (expected on 6/5/20). Importantly, this totality of evidence is not expected to be available to the public prior to the Initial Determination.” (Id. ¶ 219)

Defendants contend that these statements are not actionable under Fed. R. Civ. P. 9(b) because they are not attributed to any specific agent of Evolus. (Evolus Br. (Dkt. No. 101) at 21-22)

“[A]nonymous quotes or paraphrases of statements from alleged [corporate] insiders” will generally not suffice to plead fraud with particularity under Rule 9(b). In re Time Warner Inc. Sec. Litig., 9 F.3d 259, 264 (2d Cir. 1993); see also In re Gaming Lottery Sec. Litig., No. 96 CIV. 5567 (RPP), 1998 WL 276177, at *6 (S.D.N.Y. May 29, 1998) (“[C]orporate defendants cannot be held liable for overly optimistic statements in analysts’ articles that are not attributed to specific corporate agents.”). This rule encompasses purported direct quotes in news reports that are attributed to anonymous corporate spokesmen. See In re Time Warner, 9 F.3d at 264-66 & n.2 (affirming dismissal under Rule 9(b) of a direct quote attributed to an unnamed “Time Warner spokesman”).

Because the statements quoted above do not identify the alleged Evolus spokesperson, they provide no basis for liability under Section 10(b), and are insufficient for purposes of Rule 9(b).

Plaintiffs argue, however, that dismissing claims premised on such statements defeat[s] the purpose of the securities laws[,] since any corporation could avoid liability under the 1934 Act through the abuse of Rule 9(b)[] by simply issuing false and misleading statements through an anonymous spokesperson instead of a named officer or director.

(Pltf. Opp. (Dkt. No. 108) at 19 n.5 (quoting In re AnnTaylor Stores Sec. Litig., 807 F. Supp. 990, 1004 (S.D.N.Y. 1992))

But the Second Circuit rejected this same argument in Time Warner, where plaintiffs argued that

[a] scheming corporation could inflate its stock price through fraudulent statements whispered to reporters or analysts. If the reporters or analysts refused to reveal their sources and if no one inside the corporation leaked to the stockholders or to regulators the identity of the speakers, the corporation would have perpetuated a fraud that could not be remedied by a private civil action under the federal securities laws. For several reasons, however, we have some confidence that this is not a sufficiently likely scenario to justify a rule that would permit a suit alleging unattributed statements to survive a motion to dismiss.

As an initial matter, the function of financial reporters and security analysts is to determine the truth about the affairs of publicly traded companies. Few reporters or analysts would knowingly abet a fraud, and many will detect and reveal a corporation's efforts to use them as a channel for fraudulent statements. Additionally, investors tend to discount information in newspaper articles and analyst reports when the author is unable to cite specific, attributable information from the company. Thus, the opportunity to manipulate stock prices through the planting of false stories is somewhat limited. Finally, the effect of a less strict construction of Rule 9(b) would be only to allow discovery on the issue of the linkage between the corporation and the newspaper stories or analyst reports. Sometimes, of course, plaintiff's counsel would be able to use discovery to determine the identity of the speaker, and would find that this speaker was a person for whom the corporation was responsible. But far more often, we suspect, this would not be the case.

In re Time Warner, 9 F.3d at 265-66.

Accordingly, Plaintiffs' Section 10(b) claim will be dismissed to the extent it is premised on the three statements quoted above.

b. Alleged Statements of Opinion

Defendants argue that statements in which they express confidence in the outcome of the ITC litigation constitute opinions, rather than statements of historical fact, and thus are not actionable. (Evolus Br. (Dkt. No. 101) at 36)

i. Applicable Law

Statements of opinion "include subjective statements that reflect judgments as to values that [are] not objectively determinable." In re Gen. Elec. Co. Sec. Litig., 856 F. Supp. 2d 645, 653 (S.D.N.Y. 2012) (citation and quotation marks omitted). Similarly, "[s]tatements that 'express expectations about the future rather than presently existing, objective facts' are . . . statements of opinion." In re Aratana Therapeutics Inc. Sec. Litis., No. 17 CIV. 880 (PAE), 2018 WL 2943743, at *15 (S.D.N.Y. June 11, 2018) (quoting Fialkov v. Alcobra Ltd., No. 14 CIV. 09906 (GBD), 2016 WL 1276455, at *6 (S.D.N.Y. Mar. 30, 2016)). "Such statements, often marked by phrases such as 'I believe,' are inactionable so long as the speaker actually held

the belief professed, did not supply an untrue supporting fact, and did not omit information rendering the statement misleading.” Id. (citing Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1332 (2015)).

In order to adequately allege that a statement of opinion was misleading because it omitted material information,

[t]he investor must identify particular (and material) facts going to the basis for the issuer’s opinion – facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have – whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.

Tongue v. Sanofi, 816 F.3d 199, 209 (2d Cir. 2016) (quoting Omnicare, 135 S. Ct. at 1332).

Establishing liability on such a theory “‘is no small task,’” however. Id. (quoting Omnicare, 135 S. Ct. at 1332). “[R]easonable investors understand that opinions sometimes rest on a weighing of competing facts”; therefore, “a statement of opinion ‘is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way.’” Id. at 210 (quoting Omnicare, 135 S. Ct. at 1329). Moreover, “‘an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame.’” Id. (quoting Omnicare, 135 S. Ct. at 1330). “The core inquiry is whether the omitted facts would ‘conflict with what a reasonable investor would take from the statement itself.’” Id. (quoting Omnicare, 135 S. Ct. at 1329).

ii. Analysis

Plaintiffs do not meaningfully contest that most of Defendants’ statements concerning the ITC litigation constitute opinion. (See Pltf. Opp. (Dkt. No. 108) at 17-24) This Court concludes that Defendants’ assertions that the ITC case is “completely without merit,” that Evolus is “confident” in its intellectual property, and that the Company “believes in the merits of

[its] case,” reflect subjective and partially forward-looking evaluations of Evolus’s likelihood of success in the ITC litigation, and thus constitute opinion.

The Court has already found insufficient two of the statements challenged by Plaintiffs, which appeared in StatNews, and which are attributed to unidentified Evolus spokesmen. As discussed above, in a February 4, 2019 StatNews article, “[a]n Evolus spokesman” was quoted as saying that the claims against Jeuveau before the ITC “are ‘completely without merit’” and reflected Allergan and Medytox’s desire “to stifle competition.” (Am. Cmpl. (Dkt. No. 70) ¶ 180) (emphasis omitted) Similarly, in a March 4, 2019 StatNews article, “an Evolus spokeswoman” was quoted as saying that the Company “remain[ed] confident in [its] intellectual property and proprietary manufacturing process,” “believe[d] that Allergan and Medytox’s claims are completely without merit,” and viewed the ITC complaint as an attempt to stifle competition. (Id. ¶ 184) (emphasis omitted)

The March 4, 2019 statement at issue was issued three days after the ITC announced that it was initiating an investigation (id. ¶ 10), and the Amended Complaint does not plead facts demonstrating that Defendants were aware of the truth of the misappropriation allegations at this point. Indeed, the Amended Complaint contends that Defendants became aware of the truth of the misappropriation allegations as the result of fact discovery conducted during the ITC litigation. (See id. ¶¶ 201, 214, 218, 220, 222, 224, 226)

In arguing that Defendants – as of March 4, 2019 – had “no reasonable basis to believe” that Evolus would be successful in the ITC litigation, Plaintiffs rely on CW1’s statement that

the Company did not investigate the allegations that Jeuveau was the product of misappropriation. CW1 stated that the Company had no interest in investigating the incredible claim that Jeuveau was discovered in the soil in Korea because it would not be beneficial for Evolus to know that Jeuveau was misappropriated.

(Id. ¶ 126) (emphasis omitted)

Failing to investigate an allegation of wrongdoing is not the same as being aware of evidence that would substantiate the allegation, however. And the Amended Complaint pleads no facts suggesting that, in early March 2019, Defendants were aware of evidence that corroborated the misappropriation allegations. While Allergan and Medytox had asserted that Daewoong’s claim that it had discovered a “Hall A-hyper strain” a “in the soil in Korea” was scientifically impossible (see id. ¶ 84), their assertion did not establish that Daewoong’s BTX strain had been misappropriated from Medytox.

Moreover, acknowledging the Amended Complaint’s allegation that Evolus never investigated Allergan and Medytox’s assertions of misappropriation, the Amended Complaint does not explain what such an investigation would have uncovered. Even assuming that Evolus could have analyzed the genetic makeup of the BTX strain it had obtained from Daewoong, the Amended Complaint does not plead facts suggesting that an appropriate comparison sample from Medytox would have been available, such that Evolus could have conducted internally the genetic analysis that ultimately convinced the ITC ALJ that Daewoong’s BTX strain was derived from Medytox’s BTX strain.⁶

⁶ Citing a Citizen Petition that Medytox filed with the FDA in 2017 regarding Evolus’s Biologics License Application for Jeuveau, Plaintiffs contend that Evolus could have “perform[ed] a DNA SNP analysis of the genome for Jeuveau’s BTX strain to determine its true origin,” and that “[t]his is not a difficult task and could be performed by a single laboratory with the latest analysis software.” (Pltf. Opp. (Dkt. No. 108) at 33 (citing Rosenberg Decl., Ex. N (Dec. 5, 2017 Medytox Petition) (Dkt. No. 102-14) at 21)) However, the Medytox Citizen Petition merely asserts that such an analysis would demonstrate whether Jeuveau was derived from a “type A Hall strain” of C. botulinum that was created in a laboratory. (Rosenberg Decl., Ex. N (Dec. 5, 2017 Medytox Petition) (Dkt. No. 102-14) at 3-4, 21) While such a determination would undermine Daewoong’s claim that its BTX strain had been “isolated from soil in South Korea,” it would not demonstrate that Daewoong’s BTX strain had been derived from Medytox’s BTX strain. (Id. at 4) In sum, the easily performed laboratory analysis posited by Plaintiffs is

In short, Plaintiffs’ failure to investigate argument must be weighed in light of the evidence available to Defendants at the time. In addition to Defendants’ lack of access to the Medytox BTX strain, the Amended Complaint does not plead facts suggesting that Defendants had access to (1) Daewoong’s manufacturing process for its BTX product; (2) documentation regarding the origin of that process prior to 2013; (3) BK Lee’s connections with Daewoong; (4) information concerning Medytox’s manufacturing process for its BTX product; or (5) BK Lee’s employment at Medytox.

Medytox initiated litigation against Evolus in 2017, and it appears highly unlikely that it would have provided Evolus with genetic samples of its BTX strain in 2019 in order to assist Evolus in conducting an internal investigation. As for Defendants’ contacts with Daewoong – the company that sold Evolus the license to use its BTX strain to produce Jeuveau – the Amended Complaint pleads no facts suggesting that Daewoong had informed Evolus that the BTX strain for Jeuveau it had licensed had been misappropriated from Medytox. Nor is it plausible that Daewoong would have done so.

In sum, the practical difficulties associated with an investigation of the misappropriation allegations must be weighed against Plaintiffs’ argument that Defendants were reckless in failing to conduct an investigation.

And as to the Individual Defendants, the Amended Complaint pleads nothing as to a failure to investigate. CW1 states generically that “the Company had no interest in investigating” the misappropriation allegations (*id.* ¶ 126), but reports no communications or discussions between CW1 and Rui Avelar – to whom CW1 reported – or between CW1 and the

not comparable to the direct genetic comparison of the Daewoong and Medytox BTX strains that was presented to the ITC ALJ, and the probative value of such an analysis is not comparable to the probative value of the direct genetic comparison presented to the ITC ALJ.

other two Individual Defendants, concerning this subject. In sum, the Amended Complaint does not plead facts sufficient to demonstrate that the Individual Defendants had a culpable intent to “remain willfully ignorant” of the misappropriation allegations. (*Id.* ¶ 181)

More broadly, the Amended Complaint does not plead facts sufficient to demonstrate that the unidentified Evolus spokespersons referenced in the February and March 2019 StatNews article subjectively disbelieved their alleged statements, supplied an untrue supporting fact, or omitted information that rendered the statements misleading.

The Amended Complaint also cites the following statements that Defendants made between August 12, 2019 and May 11, 2020 regarding the ITC litigation:

- Defendant Moatazedi’s remarks on an August 12, 2019 earnings call with securities analysts: “I know there’s a lot of interest around the legal case. Look, we’re not going to be in a position to comment about the specifics as the case continues to unfold. As we’ve said from the beginning, we remain very confident in our IP, and we’ll let the court system continue to work through the case.” (Am. Cmplt. (Dkt. No. 70) ¶ 200) (emphasis omitted)
- Defendant Moatazedi’s remarks on a February 25, 2020 earnings call with securities analysts: “Lastly, I’d like to provide an update on the International Trade Commission, or ITC case. As you may know, the ITC hearings took place February 4 through 7 in Washington D.C. In June, the judge will reach an initial determination, followed by a final decision by the ITC targeted for October 2020. In the interim, it’s customary for various redacted versions of motions, briefs and transcripts to become public. However, I would caution you not to draw any definite conclusions from individual documents, as the initial determination will be decided based on the totality of the merits as assessed by the judge in June and the ITC in October. We look forward to resolving the case before year end and remain confident in the strength of our IP. We can’t speak further to this matter on today’s call, but recognize it is something important to all of our employees and to our shareholders. . . . As we mentioned earlier, the hearings took place earlier in February. And with the ITC, the majority of those hearings are confidential, it’s not like a public trial where most of the information is available to you. So unfortunately . . . I am not able to provide any more color than what I provided earlier. That being said, nothing changed through the case, we feel confident in the strength of our IP and we expect that this case will be

resolved before the end of the year and this will be behind us.” (*Id.* ¶¶ 212-13) (emphasis omitted)

- Evolus’s March 4, 2020 press release: “In several media reports this week, Medytox has made comments on the International Trade Commission (ITC) case, which Evolus believes are speculative and intended to create confusion in the U.S. market ahead of the ITC Judge’s initial determination in June 2020 and the ITC’s final determination, which is targeted for October 2020. . . . The ITC Judge will make his own independent decision based upon all the evidence presented at the hearing and through all the parties’ filings. The Judge assigned to the ITC is not obligated to accept a staff attorney’s position on the facts, and it’s fairly common for the Judge and the staff attorney to disagree on substantive matters. Evolus and Daewoong remain confident in the strength of our intellectual property and will continue to vigorously defend it through the entirety of the ITC process.” (*Id.* ¶ 217) (emphasis omitted)
- Defendant Silvernail’s March 11, 2020 remarks at a global healthcare conference, in which she said the following about the status of the ITC investigation: “I think if you look through it all and you look through all the information that is out there, it’s very contradictory. And so I’d be careful about drawing any conclusions about who sided with whom on what. There just is a tremendous amount of information coming out and will come out over the next 90 days or so. And we believe in the merits of our case, we’re confident in our IP. But it’s hard to comment on each individual fact that’s going to come out. Some of them are going to look like the case is swinging to Daewoong and some are going to make it look like it’s swinging to Medytox. . . . As I mentioned earlier, when you look at the case, there will be a preliminary decision in June and a final decision in October. If there is a settlement, it will be between Medytox and Daewoong. And only they can really comment on that, and so we won’t be commenting on settlement today at all. For us, we have – we are in a very solid position. We like our odds in this. We believe in the merits of our case and are very confident in the IP. So we are not really worried about the outcome here.” (*Id.* ¶¶ 221, 223) (emphasis omitted)
- Defendant Moatazedi’s remarks on a May 11, 2020 earnings call with securities analysts: Moatazedi stated that he “remain[s] confident in the strength of our IP.” (*Id.* ¶ 225) (emphasis omitted)

Plaintiffs contend that Defendants had “no reasonable basis” to make these statements, because by the close of discovery in the ITC case on October 30, 2019 – and a fortiori by the time of the ITC ALJ’s evidentiary hearing in early February 2020 – Defendants

“knew” that the BTX strain used in Jevueau had been misappropriated by Daewoong. (Id. ¶ 201, 214, 218, 220, 222, 224, 226)

Plaintiffs’ allegations are insufficient for several reasons. As an initial matter, the Amended Complaint pleads no facts suggesting that the Individual Defendants were aware of any particular item of discovery produced in the ITC litigation. Similarly, the Amended Complaint does not plead facts suggesting that any Individual Defendant was involved in supervising those Evolus employees with knowledge of the ITC litigation or in monitoring the progress of the case. Instead, Plaintiffs assert that because of the importance of the ITC litigation, Defendants “‘must have educated’” themselves about the details of the case before speaking about it publicly. (Pltf. Opp. (Dkt. No. 108) at 33 (quoting In re Gen. Elec. Co. Sec. Litig., 857 F. Supp. 2d 367, 395 (S.D.N.Y. 2012))) But this is mere speculation, particularly given the restrictions imposed by the ITC ALJ concerning the dissemination of confidential business information.

As discussed above, under the ITC ALJ’s protective order, only Evolus’s outside counsel was allowed to have access to the confidential business information of other entities. Accordingly, Defendants would have had no access to confidential business information produced by Medytox, Daewoong, or Allergan. (See Rosenberg Decl., Ex. P (Mar. 5, 2019 ITC Prot. Order) (Dkt. No. 102-16) ¶¶ 1, 3; see also Pltf. Opp. (Dkt. No. 108) at 30 (noting that “only Evolus’s lawyers had access to the substance of Medytox’s trade secrets”) Given that the determinations of the ALJ and the ITC turned on confidential business information – including the genetic makeup of the BTX strains, and the details concerning Daewoong’s and Medytox’s manufacturing processes – Defendants lacked access to the most relevant evidence during the Class Period. Moreover, the Amended Complaint does not explain what conclusions Defendants

should have drawn from the non-confidential discovery, and how that evidence bears on Evolus’s likelihood of success in the ITC litigation.

The ITC ALJ’s three-day evidentiary hearing between February 4, 2019 and February 7, 2019 was subject to the same restrictions concerning confidential business information. (*Id.* ¶ 116)⁷ While Evolus’s general counsel, Jeff Plumer, attended the hearing, the transcript indicates that “corporate people” such as Plumer were asked to leave the hearing during “confidential sessions” that involved discussion of confidential business information. (Rosenberg Decl., Ex. V (Feb. 4, 2020 ITC Hrg. Tr.) (Dkt. No. 102-22) at 11, 18) As with the non-confidential materials produced in discovery, the Amended Complaint does not explain what evidence at the evidentiary hearing Defendants would have had access to, and what conclusions they should have drawn based on that evidence.

Plaintiffs instead speculate that Evolus’s outside counsel “doubtlessly shared the import of the evidence with Defendants.” (Pltf. Opp. (Dkt. No. 108) at 30) But outside counsel was not permitted to share with Defendants the most significant evidence offered at the evidentiary hearing, and the Amended Complaint – understandably – does not allege what Evolus’s outside counsel told Defendants about the Company’s likelihood of success. It is obvious from the record that the issues addressed by the ALJ and later by the ITC were extremely complex – requiring a 282-page Final Initial Determination – scientific in nature, and

⁷ For example, while Allergan and Medytox’s expert witness, Dr. Keim, testified in an “open” session that it was his opinion that “the Daewoong [BTX] strain came from or was derived from the Medytox [BTX] strain” (Rosenberg Decl., Ex. V (Feb. 4, 2020 ITC Hrg. Tr.) (Dkt. No. 102-22) at 18), Defendants had no access to the genetic analysis that was the basis for Dr. Keim’s opinion. And Defendants’ expert, of course, disputed Dr. Keim’s assertions. (*See* Am. Cmplt., Ex. B (July 6, 2020 FID, Public Version) (Dkt. No. 70-2) at 101-07)

– given the disparate results before the ALJ and the ITC – involved matters about which reasonable minds could differ.

The ALJ’s conclusions regarding the genetic similarity between the Daewoong and the Medytox BTX strains involved highly complex scientific analysis about which the parties’ experts profoundly disagreed. (See Am. Cmplt., Ex. B (July 6, 2020 FID, Public Version) (Dkt. No. 70-2) at 101-07) And the ALJ’s conclusion that Daewoong misappropriated Medytox’s manufacturing process drew on three disparate sources of evidence: “(1) the similarity of Daewoong’s process to Medytox’s; (2) the lack of evidence of Daewoong’s independent development; and (3) the implausibly fast timeline by which Daewoong achieved BTX production at commercial scale.” (Id. at 139) The ALJ’s findings of fact concerning this issue are nearly 20 pages long and draw heavily from redacted confidential information. (Id. at 140-59) And the ALJ ultimately agreed with Daewoong and Evolus that Medytox and Allergan had not demonstrated that BK Lee misappropriated trade secrets from Medytox – a key allegation dating back to Medytox’s allegations in the 2017 lawsuits filed in California and South Korea. (Id. at 99-101, 139)

In addition to the dispute regarding misappropriation, the ITC litigation involved a host of other complex issues, including whether the allegedly misappropriated materials constituted protectable trade secrets. (Am. Cmplt., Ex. B (July 6, 2020 FID, Public Version) (Dkt. No. 70-2) at 69-99, 120-134) Analysis of the trade secret issue required more than 40 pages in the FID. The ALJ, and later the ITC, was also called upon to resolve Evolus’s arguments regarding subject matter jurisdiction (id. at 29-35), standing (id. at 35-45), the existence of Allergan’s domestic industry (id. at 152-159), whether Allergan could show that its

domestic industry was being substantially injured (id. at 197-232), the statute of limitations (id. at 232-242), laches (id. at 242-250), and unclean hands. (Id. at 250-257)

In sum, the Amended Complaint does not plead facts sufficient to demonstrate that – after the close of discovery and the February 2020 evidentiary hearing – Evolus’s outside counsel “must” have advised Defendants that Evolus would not prevail in the ITC litigation. The case was too complicated; the issues were too numerous; and the prospect of success or failure was too contingent. Indeed, Evolus prevailed on a number of the key issues in the ITC litigation, including as to whether BK Lee had misappropriated trade secrets from Medytox, and whether Medytox’s BTX strain was a trade secret. The fact that Evolus was ultimately subjected to a twenty-one month importation ban and cease-and-desist order does not demonstrate that this outcome was inevitable, or that Defendants could not have had a reasonable, good faith belief that they would prevail in the ITC litigation.

The fact that the ITC staff attorney sided with Medytox on the misappropriation issues after the evidentiary hearing (see Am. Cmplt. (Dkt. No. 70) ¶ 216) does not alter this conclusion. While the Amended Complaint cites data suggesting that ITC ALJs “heavily weigh the opinion of ITC staff attorneys in deciding cases,”⁸ Plaintiffs do not dispute that it was accurate for Defendants to say – in their March 4, 2019 press release – that

[t]he ITC Judge will make his own independent decision based upon all the evidence presented at the hearing and through all the parties’ filings. The Judge assigned to the ITC is not obligated to accept a staff attorney’s position on the facts, and it’s fairly common for the Judge and the staff attorney to disagree on substantive matters.

⁸ Id. ¶ 94 & n.12 (citing Jerold B. Murphy, A Statistical Comparison of the Staff Attorneys’ Position on Disputed Issues and the Administrative Law Judges’ Decisions on Such Issues, 21 337 REPORTER 53, 54 (2005))

(Id. ¶ 217) In sum, while the ITC staff attorney’s stance weighed against Evolus’s overall chance of success in the ITC proceeding, it was not so detrimental that Defendants no longer had a reasonable basis for statements such as “[w]e believe in the merits of our case”; “[we] are very confident in the IP”; and “[w]e are not really worried about the outcome here.” (Id. ¶ 223)

For all the reasons discussed above, the Court concludes that the Amended Complaint does not adequately allege that Defendants subjectively disbelieved the statements cited above, that they supplied an untrue supporting fact, or that they omitted information that rendered the statements misleading.

The Amended Complaint also challenges three statements Defendants made about the ITC litigation on February 25, 2020 and March 4, 2020 – after the evidentiary hearing – in which they stated that “nothing has changed”:

- Defendant Moatazedi’s remarks on a February 25, 2020 earnings call with securities analysts: “As we mentioned earlier, the hearings took place earlier in February. And with the ITC, the majority of those hearings are confidential, it’s not like a public trial where most of the information is available to you. So unfortunately . . . I am not able to provide any more color than what I provided earlier. That being said, nothing changed through the case, we feel confident in the strength of our IP and we expect that this case will be resolved before the end of the year and this will be behind us.” (Am. Cmplt. (Dkt. No. 70) ¶ 213) (emphasis omitted)
- Evolus’s March 4, 2020 press release stating: “In several media reports this week, Medytox has made comments on the International Trade Commission (ITC) case, which Evolus believes are speculative and intended to create confusion in the U.S. market ahead of the ITC Judge’s initial determination in June 2020 and the ITC’s final determination, which is targeted for October 2020. Importantly, nothing has changed as a result of the media reports from Korea. The ITC Judge will make his own independent decision based upon all the evidence presented at the hearing and through all the parties’ filings. The Judge assigned to the ITC is not obligated to accept a staff attorney’s position on the facts, and it’s fairly common for the Judge and the staff attorney to disagree on substantive matters. Evolus and Daewoong remain confident in the strength of our intellectual property and will continue to vigorously defend it through the entirety of the ITC process.” (Id. ¶ 217) (emphasis omitted).

- A March 4, 2020 Cantor Fitzgerald analyst report, which cited “conversations with management” at Evolus and stated that: “Our key takeaway is that nothing has changed as a result of Korean media reports. The judge will make the Initial Determination based on the totality of evidence (expected on 6/5/20). Importantly, this totality of evidence is not expected to be available to the public prior to the Initial Determination.” (*Id.* ¶ 219)

Defendants’ assertions that “nothing has changed” in the ITC litigation constitute a subjective expression of Defendants’ confidence in their position, as well as a factual statement about the procedural posture of the ITC litigation. Whether viewed as a factual statement or as an opinion, none of these statements is false or misleading. Each of the three statements accurately describes the procedural posture of the ITC litigation – *i.e.*, that the evidentiary hearing had concluded and that the parties were awaiting the ALJ’s Final Initial Determination. And to the extent that the assertion “nothing has changed” could be interpreted as Defendants’ expressing confidence in the strength of their legal position, the Amended Complaint does not plead facts demonstrating that Defendants no longer believed in their legal position, or had omitted information that rendered their statements misleading.

The Court concludes that none of the ITC litigation-related statements discussed above is actionably false or misleading.⁹

2. Statements that the Jeuveau Is a “Proprietary” Formulation

Plaintiffs challenge statements that Evolus made during the Class Period in which it described Jeuveau as a “proprietary 900 kDa purified botulinum toxin type A formulation.” (Rosenberg Decl., Ex. A (Feb. 1, 2019 press release) (Dkt. No. 102-1) at 2; *see* Am. Cmpl. (Dkt. No. 70) ¶¶ 177, 186, 194, 190, 196, 202, 205, 211, 225) Plaintiffs contend that these statements

⁹ Given this finding, the Court does not reach Defendants’ argument that certain of these statements constitute puffery or forward-looking statements under the PSLRA’s safe harbor. (*See* Evolus Br. (Dkt. No. 101) at 20-22, 25-26)

are materially false and misleading, because “the BTX strain and the manufacturing process used to manufacture Jeuveau [were] illegally misappropriated from Medytox,” and were therefore not “proprietary” to Evolus or to Daewoong. (Am. Cmplt. (Dkt. No. 70) ¶ 178)

Defendants contend that these statements constitute “nonspecific puffery,” because they are too general to mislead a reasonable investor. (Evolus Br. (Dkt. No. 101) at 22-24)

a. Applicable Law

“Puffery” includes “statements [that] are too general to cause a reasonable investor to rely upon them,” ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 206 (2d Cir. 2009), and thus “cannot have misled a reasonable investor.” San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 811 (2d Cir. 1996). Such statements “‘lack the sort of definite positive projections that might require later correction.’” Id. (quoting In re Time Warner, 9 F.3d at 259, 267).

“[E]xpressions of puffery and corporate optimism do not give rise to securities violations. Up to a point, companies must be permitted to operate with a hopeful outlook: People in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage.”

Nguyen v. New Link Genetics Corp., 297 F. Supp. 3d 472, 488 (S.D.N.Y. 2018) (quoting Rombach, 355 F.3d at 174).

“On the other hand, pollyannaish statements couched as rosy corporate-speak may be actionable if they contradict facts known to a defendant,” id., “if they are worded as guarantees or are supported by specific statements of fact, or if the speaker does not genuinely or reasonably believe them.” IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC, 783 F.3d 383, 392 (2d Cir. 2015) (internal quotation marks

and citations omitted). Although there is no definitive test to determine how vague a statement must be to qualify as puffery, “statements expressing a general view that ‘things are going well,’ that the company is ‘well positioned,’ or that a year was ‘successful’ are generally not actionable.” In re Nevsun Res. Ltd., No. 12 CIV. 1845 PGG, 2013 WL 6017402, at *10 (S.D.N.Y. Sept. 27, 2013).

b. Analysis

Plaintiffs contend that the term “proprietary” is not puffery because it has a specific legal meaning which is highly material given this context – a lawsuit alleging misappropriation of intellectual property. Because Defendants repeatedly cited their 900 kDa proprietary formulation as the only neurotoxin product on the market competing with BOTOX as the sole basis for their success, while failing to disclose their illegal misappropriation, their representations of Jevueau as proprietary cannot be deemed puffery.

(Pltf. Opp. (Dkt. No. 108) at 28)

The Amended Complaint provides the following dictionary definition of “proprietary”: “something that is used, produced, or marketed under exclusive legal right of the inventor or maker.” (Am. Cmplt. (Dkt. No. 70) ¶ 174 (citing Proprietary, Merriam-Webster (last visited September 25, 2024), available at <https://www.merriam-webster.com/dictionary/proprietary>)) Black’s Law Dictionary defines “proprietary” as (1) “[o]f, relating to, or involving a proprietor <the licensee’s proprietary rights>”; (2) “[o]f, relating to, or holding as property <the software designer sought to protect its proprietary data>”; and (3) “([o]f a product) sold under a tradename.” Proprietary, Black’s Law Dictionary (12th Ed. 2024)

As discussed above, Jevueau was developed in South Korea by Daewoong under the designation DWP-450. In September 2013, Daewoong issued an exclusive license to Evolus to market DWP-450 in the United States under the brand name Jevueau. (Am. Cmplt. (Dkt. No. 70) ¶¶ 54-55) The ITC concluded that – at some point before Daewoong and Evolus entered into

the September 2013 licensing agreement – Daewoong misappropriated from Medytox the BTX strain and manufacturing process that Daewoong had used to develop DWP-450. The ITC also concluded, however, that Medytox’s BTX strain was not a protectible trade secret, because Medytox had obtained the strain from another source. (Rosenberg Decl., Ex. W (Dec. 16, 2020 FD Opinion) (Dkt. No. 102-23) at 9-13)

The Court concludes that “proprietary” – as used in the phrase “proprietary 900 kDa purified botulinum toxin type A formulation” (Rosenberg Decl., Ex. A (Feb. 1, 2019 press release) (Dkt. No. 102-1) at 2) – is too vague to be actionable.

As an initial matter, the statement cited by Plaintiffs does not indicate proprietary to whom. Evolus does not state that the BTX formulation is proprietary to Evolus, proprietary to Daewoong, or proprietary to some other entity. As used in the phrase cited by Plaintiffs, “proprietary” conveys “special” or “unique,” “legally protected,” or subject to a license or some other legally authorized right of use. It could also be understood as suggesting that the BTX formulation is subject to trade secret protection. But the precise meaning of “proprietary” in the statement cited by Plaintiffs is not clear.

Even if the statement could be understood as connoting that Evolus was marketing the BTX formulation pursuant to a license, that understanding would be accurate. Evolus had in fact obtained an exclusive license from Daewoong to market Daewoong’s BTX formulation in the United States as Jeuveau. (Am. Cmplt. (Dkt. No. 70) ¶ 54)

In sum, the term “proprietary” – as used in the statement cited by Plaintiffs – conveys little more than that Evolus has the legal right to market Daewoong’s BTX formulation in the United States. Given that Evolus had in fact obtained a license to market Daewoong’s BTX formulation in the United States, the statement cannot be said to be false or misleading.

And the Amended Complaint's allegations of falsity "do[] not cure [the] generality" of the statement, which is "what prevents [it] from rising to the level of materiality required to form the basis for assessing a potential investment." City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG, 752 F.3d 173, 183 (2d Cir. 2014). As such, the statement is "too general to cause a reasonable investor to rely upon [it]" in the sense that Plaintiffs urge. ECA, Loc. 134 IBEW, 553 F.3d at 206.

Moreover, the Amended Complaint does not plead facts demonstrating that Defendants "did not subjectively believe" that they had a legal right to market Daewoong's BTX formulation in the United States. In re Rockwell Med., Inc. Sec. Litig., No. 16 CIV. 1691 (RJS), 2018 WL 1725553, at *8 (S.D.N.Y. Mar. 30, 2018).

For all these reasons, the Court concludes that Evolus's statements describing Jevueau as a "proprietary formulation" are not actionable.

3. Statements About Jevueau's "Competitive Strengths"

Plaintiffs challenge several statements in Evolus's SEC filings concerning Jevueau's "competitive strengths." Evolus's Form 10-K for 2018, filed on March 20, 2019, states that the "competitive strengths" of Jevueau include that

Jevueau will offer the U.S. market the first known 900 kDa neurotoxin alternative to BOTOX. The manufacture of both Jevueau and BOTOX starts with a 900 kDa complex, includes adding the excipients human serum albumin, or HSA, and sodium chloride, and finishes by vacuum drying. We believe Jevueau is the only known neurotoxin product in the United States with a 900 kDa neurotoxin complex other than BOTOX. We also believe an important component of competitiveness in the neurotoxin market relates to the characteristics associated with the 900 kDa complex and the potential of the accessory proteins to increase the effectiveness of the active toxin portion of the complex.

(Am. Cmpl't. (Dkt. No. 70) ¶ 186) Identical statements appear in a May 15, 2019 prospectus accompanying an offering of Evolus stock by Defendant Alphaeon (id. ¶ 194), and in Evolus's Form 10-K for 2019, which the Company filed on February 25, 2020. (Id. ¶¶ 209-10)

Plaintiffs contend that these statements are misleading because Jouveau's "competitive strengths" were due to its misappropriation rather than the reasons suggested [by Evolus]." (*Id.* ¶ 187) Defendants respond that these statements are not false or misleading. (Evolus Br. (Dkt. No. 101) at 24)

a. Applicable Law

Rule 10b-5 makes it unlawful for any person to make an "untrue statement of a material fact" or to "omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading" in connection with the purchase or sale of a security. 17 C.F.R. § 240.10b-5(b).

"A statement is misleading if a reasonable investor, in the exercise of due care, would have received a false impression from the statement." Plumbers & Steamfitters Local 137 Pension Fund v. Am. Express Co., No. 15 CIV. 5999 (PGG), 2017 WL 4403314, at *11 (S.D.N.Y. Sept. 30, 2017) (internal quotation marks and citation omitted). "In general[,] there is no duty to disclose a fact . . . merely because a reasonable investor would very much like to know that fact." Meyer v. Jinkosolar Holdings Co., 761 F.3d 245, 250 (2d Cir. 2014) (internal quotation marks and citations omitted). "[D]isclosure is required," however, "when necessary to make . . . statements made, in light of the circumstances under which they were made, not misleading." *Id.* (internal quotation marks and citations omitted). In other words, "once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Id.*

"That duty is not boundless[, however]." Plumbers & Steamfitters Local 137 Pension Fund, 2017 WL 4403314, at *13 (internal quotation marks and citation omitted). "[R]evealing one fact about a subject does not trigger a duty to reveal all facts on the subject." *Id.* (quoting Richman v. Goldman Sachs Group, Inc., 868 F. Supp. 2d 261, 274 (S.D.N.Y. 2012)). "[T]he proper inquiry requires an examination of defendant's representations, taken

together and in context.” Meyer, 761 F.3d at 250-51 (quoting In re Morgan Stanley Info. Fund Sec. Litig., 592 F.3d 347, 366 (2d Cir. 2010)). “In other words, [courts] look to the total mix of available information.” Plumbers & Steamfitters Local 137 Pension Fund, 2017 WL 4403314, at *13 (internal quotation marks and citation omitted)

b. Analysis

As an initial matter, the Amended Complaint pleads no facts suggesting that Defendants’ assertions about Jeuveau’s “competitive strengths” are false. The ITC litigation addressed whether Daewoong misappropriated the BTX strain and manufacturing process for Jeuveau from Medytox. Whether Daewoong committed misappropriation has no bearing on Jeuveau’s actual formulation, the manufacturing process used to make it, or the product’s position in the market relative to BOTOX.

Evolus’s statements about Jeuveau’s “competitive strengths” are, however, potentially misleading to the extent they do not disclose the risk that a court might someday agree with Medytox’s misappropriation claim and grant Medytox and Allergan remedies impacting the commercial viability of Jeuveau in the United States. But Evolus disclosed the risk of unfavorable ITC action – and the consequences of an unfavorable ITC determination – in two of the same documents in which the “competitive strengths” statements appear. In Evolus’s Form 10-K for 2018, for example, Evolus disclosed the existence of the 2017 misappropriation lawsuits in California and South Korea, as well as Allergan and Medytox’s January 30, 2019 ITC complaint. (Rosenberg Decl., Ex. B (Evolus 2018 10-K) (Dkt. No. 102-2) at 9-10) After describing the nature of the misappropriation claims in the ITC litigation, Evolus warned that

[a]n adverse ruling by the ITC against either us or Daewoong could result in the imposition of an exclusion order which would bar imports of Jeuveau into the United States and a cease and desist order which would bar sales and marketing of our sole product Jeuveau within the United States either of which would adversely affect our ability to carry out our business and which would have an adverse

effect on our business, financial position, results of operations, or cash flows and could also result in reputational harm. Any of these consequences could adversely affect our business and results of operations.

(Id. at 10) Evolus made the same disclosure in its Form 10-K for 2019. (See Rosenberg Decl., Ex. H (Evolus 2019 10-K) (Dkt. No. 102-8) at 12-13) Given these disclosures, the statements about Jevueau’s “competitive strengths” elsewhere in the Company’s SEC filings cannot be considered misleading.

The Court concludes that the “competitive strengths” statements cited in the Amended Complaint are not actionable.¹⁰

4. Statement that Evolus “Developed” Jevueau

Plaintiffs challenge the following statement made by Defendant Avelar during a May 8, 2019 call with securities analysts:

For those of you that don’t know Evolus, the company was formed 6 years ago. The root of the name Evolus was around this concept of evolving with the market. The original founder was a former Head of R&D at Allergan, developed this neurotoxin and focused it solely on this category of medical aesthetics.

(Am. Cmpl. (Dkt. No. 70) ¶ 188) (emphasis omitted) Plaintiffs claim that this statement is false or misleading because “Defendant Avelar knew or recklessly disregarded that, the original founder of Evolus did not ‘develop[]’ this neurotoxin. Instead, Medytox developed the neurotoxin, its proprietary BTX strain, after years of research and development.” (Id. ¶ 189)

There is no dispute in the instant litigation that Evolus has consistently represented to investors that Jevueau was originally developed by Daewoong – and not by Evolus – and that Daewoong subsequently granted a license to Evolus to sell the Jevueau

¹⁰ Having concluded that the “competitive strengths” statements are not false or misleading, the Court does not reach Defendants’ argument that these statements constitute puffery. (See Evolus Br. (Dkt. No. 101) at 24)

formulation in the United States. (See, e.g., Rosenberg Decl., Ex. B (Evolus 2018 10-K) (Dkt. No. 102-2) at 6-7 (“On September 30, 2013, [Evolus] entered into a license and supply agreement, or the Daewoong Agreement, pursuant to which [Evolus has] an exclusive distribution license to Jeuveau from Daewoong Pharmaceuticals Co., Ltd., or Daewoong, a South Korean pharmaceutical manufacturer, for aesthetic indications in the United States. . . .”); Fuks Decl., Ex. 3 (Mar. 22, 2019 Evolus S-3 Registration Stmt.) at 9 (same); Rosenberg Decl., Ex. C (Feb. 1, 2018 Evolus S-1 Registration Stmt.) (Dkt. No. 102-3) at 6) (“We are reliant on the ability of Daewoong, as the licensor of our only product candidate, . . . to maintain their intellectual property and protect their intellectual property against misappropriation, infringement or other violation”); Rosenberg Decl., Ex. E (Evolus Q1 2019 10-Q) (Dkt. No. 102-5) at 5 (noting that in the 2017 California lawsuit, “Medytox claims that as a result of Daewoong’s conduct, [Evolus] entered into the Daewoong Agreement [to license Jeuveau] instead of an agreement with Medytox to license Meditoxin”))

Given Evolus’s frequent and accurate disclosures about how it acquired the right to market Jeuveau in the United States, Defendant Avelar’s statement on the analyst call – when “taken together and in context” with these other statements, Meyer, 761 F.3d at 250-51 – cannot be regarded as an attempt to falsely represent to investors Evolus’s role in the development of Jeuveau. Nor, given this larger context, would a reasonable investor “have received a false impression from the statement.” Plumbers & Steamfitters Local 137 Pension Fund, 2017 WL 4403314, at *11.

* * * *

The Court concludes that the alleged misstatements cited in the Amended Complaint are not actionably false or misleading. As discussed below, even if the alleged

misstatements were actionable, Plaintiffs' Section 10(b) claim would still fail, because the Amended Complaint does not adequately plead scienter.

C. Scienter

Defendants contend that the Amended Complaint does not adequately plead scienter as to any Defendant. (Evolus Br. (Dkt. No. 101) at 27-35; Alphaeon Br. (Dkt. No. 104) at 16-21)

1. Applicable Law

To plead scienter, the PSLRA requires that a plaintiff "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "Under this heightened pleading standard for scienter, a 'complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" Slayton v. Am. Exp. Co., 604 F.3d 758, 766 (2d Cir. 2010) (quoting Tellabs, 551 U.S. at 324). "In determining whether a strong inference exists, the allegations are not to be reviewed independently or in isolation"; rather, "the facts alleged must be 'taken collectively.'" Id. (quoting Tellabs, 551 U.S. at 322-23).

"The plaintiff may satisfy [this pleading] requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." ATSI Commc'ns, 493 F.3d at 99. "[I]f Plaintiffs cannot make [a] 'motive' showing, then they [can] raise a strong inference of scienter under the 'strong circumstantial evidence' prong, 'though the strength of the circumstantial allegations must be correspondingly greater' if there is no motive." ECA v. JP Morgan Chase, 553 F.3d 187, 198-99 (2d Cir. 2009) (quoting Kalnit v. Eichler, 264 F.3d 131, 142 (2d Cir. 2001)).

“Motive to commit fraud entails ‘concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged.’” Cannavest, 307 F. Supp. 3d at 244 (quoting Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir. 2000)). In alleging motive, “[a] plaintiff may not rely on ‘motives possessed by virtually all corporate insiders,’ . . . [and] instead must allege ‘that defendants benefitted in some concrete and personal way from the purported fraud.’” Id. (quoting Novak, 216 F.3d at 307-08). Generic motives, such as “‘the desire for the corporation to appear profitable,’ as well as ‘the desire to keep stock prices high to increase officer compensation,’ are ‘insufficient[.]’” Id. (quoting Kalnit, 264 F.3d at 139)

To plead conscious misbehavior or recklessness, Plaintiffs must allege conduct that is, “at the least . . . highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.” Kalnit, 264 F.3d at 142 (internal quotation marks and citation omitted). “An egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of . . . recklessness.” Chill v. Gen. Elec. Co., 101 F.3d 263, 269 (2d Cir. 1996) (citation and quotation marks omitted). “The plaintiff may allege that the defendants ‘knew facts or had access to information suggesting his public statements were not accurate, or failed to check information that he had a duty to monitor.’” Blank v. TriPoint Glob. Equities, LLC, 338 F. Supp. 3d 194, 214 (S.D.N.Y. 2018) (quoting Nathel v. Siegal, 592 F. Supp. 2d 452, 464 (S.D.N.Y. 2008)). “Although this is a highly fact-based inquiry, . . . ‘[s]ecurities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants’ knowledge of facts or access to information contradicting their public statements.’” Kalnit, 264 F.3d at 142 (quoting Novak, 216 F.3d at 308).

2. Analysis

a. Motive and Opportunity

Plaintiffs contend that Evolus stock sales by Defendants Alphaeon, Silvermail, and Avelar support an inference of scienter. (Pltf. Opp. (Dkt. No. 108) at 35-36) The sales cited by Plaintiffs are listed below:

Defendant	Date	# of Shares	Proceeds
Alphaeon	5/20/2019	4,000,000	\$77,000,000.00
Alphaeon	5/20/2019	1,017,000	\$19,577,250
Alphaeon	5/22/2019	290,518	\$5,592,471.59
Lauren Silvermail	5/31/2019	2,612	\$35,340.36
Alphaeon	6/3/2019	1,299,000	\$25,005,750.00
Rui Avelar	1/7/2020	39,442	\$422,423.82

(See Am. Cmplt. (Dkt. No. 70) ¶ 228)

“The mere fact that insider stock sales occurred does not suffice to establish scienter.” In re Gildan Activewear, Inc. Sec. Litig., 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009) (citation and quotation marks omitted). Rather, Plaintiffs “must establish that the sales were ‘unusual’ or ‘suspicious.’” Id. In determining whether stock sales are unusual or suspicious, courts consider “(1) the amount of net profits realized from the sales; (2) the percentages of holdings sold; (3) the change in volume of insider defendant’s sales; (4) the number of insider defendants selling; (5) whether sales occurred soon after statements defendants are alleged to have known were misleading; (6) whether sales occurred shortly before corrective disclosures or materialization of the alleged risk; and (7) whether sales were made pursuant to trading plans such as Rule 10b5-1 plans.” Gagnon v. Alkermes PLC, 368 F. Supp. 3d 750, 772-73 (S.D.N.Y. 2019) (citation and quotation marks omitted).

Between May 20, 2019 and June 3, 2019, Defendant Alphaeon sold 6.6 million shares of Evolus stock, representing about 43% of its holdings, and received proceeds of

approximately \$121 million. (Am. Cmplt. (Dkt. No. 70) ¶ 229) Defendant Avelar sold 39,442 shares of Evolus stock during the Class Period, representing about 36% of his holdings, and received proceeds of \$422,423.82. (Id. ¶ 230) Defendant Silvernail sold 2,619 shares of Evolus stock, representing about 9.5% of her holdings, and received proceeds of \$35,340.36. (Id. ¶ 228; Rosenberg Decl., Ex. BB (May 31, 2024 Silvernail Form 4) (Dkt. No. 102-28) at 2).

The Amended Complaint does not plead facts demonstrating that the timing of these sales is suspicious. As an initial matter, all but Avelar's stock sale occurred more than a year before the end of the Class Period in July 2020. Moreover, as discussed above, the Amended Complaint does not adequately allege that Defendants made any actionable false or misleading statements. And even if the statements cited by Plaintiffs were actionable, Plaintiffs have not pled facts showing that Defendants' stock sales took place after they issued false or misleading statements that could have inflated the Evolus share price.

According to the Amended Complaint, Defendants learned the truth about Daewoong's misappropriation of Medytox's BTX strain as a result of the discovery and February 2020 evidentiary hearing in the ITC litigation. (Am. Cmplt. (Dkt. No. 70) ¶¶ 201, 214, 218, 220, 222, 224, 226) But all of Defendants' stock sales – other than Avelar's – occurred before the close of fact discovery on July 19, 2019, and eight months before the February 2020 evidentiary hearing. (Id. ¶ 114) In sum, the Amended Complaint does not plausibly allege that Defendants were aware of the truth of Medytox's misappropriation allegations at the time they sold their Evolus stock.

As for Defendant Avelar, he sold shares on January 7, 2020 – before the evidentiary hearing – pursuant to a Rule 10b5-1 trading plan that he adopted “in the fourth quarter of 2019.” (Rosenberg Decl., Ex. FF (Jan. 8, 2020 Avelar Form 4) (Dkt. No. 102-32) at 2)

The Amended Complaint does not plead facts demonstrating that Avelar was aware of the evidence produced in discovery during the ITC litigation. And, as discussed above in connection with Defendants’ alleged false statements, the Amended Complaint does not plead facts demonstrating that – by the fourth quarter of 2019 or early January 2020 – the Company’s outside counsel “must” have advised senior managers such as Avelar that (1) Jouveau was the result of a misappropriated BTX strain; or (2) Evolus would not prevail in the ITC litigation.

As for Defendant Silvernail, she sold 2,619 shares of Evolus stock on May 31, 2019, which represented only about 9.5% of her holdings. (Rosenberg Decl., Ex. BB (May 31, 2020 Silvernail Form 4) (Dkt. No. 102-28) at 2) Her sale of Evolus stock does not support a strong inference of scienter. See Rothman v. Gregor, 220 F.3d 81, 95 (2d Cir. 2000) (inference of scienter weakened by sale of “only about 9.3 percent” of the defendant’s holdings); In re Oxford Health Plans, Inc., 187 F.R.D. 133, 140 (S.D.N.Y. 1999) (“[W]here a corporate insider sells only a small fraction of his or her shares in the corporation, the inference of scienter is weakened.”).

Finally, Defendant Moatazedi – Evolus’s chief executive officer and the person who made or authorized most of the alleged false statements – is not alleged to have sold any Evolus shares during the Class Period, which further weakens any inference of scienter. See In re Keyspan Corp. Sec. Litig., 383 F. Supp. 2d 358, 383-84 (E.D.N.Y. 2003) (“As chairman and CEO of the Company, and as the individual who actually made most of the alleged misstatements during the class period, defendant [CEO], if anyone, was surely well-positioned to reap profits from insider knowledge.”); In re eSpeed, Inc. Sec. Litig., 457 F. Supp. 2d 266, 289 (S.D.N.Y. 2006) (“[T]he fact that neither [the chief financial officer] nor [the chief executive officer] sold stock during the putative class period undermines plaintiffs’ motive allegations

against defendants.”); see also Acito v. IMCERA Grp., Inc., 47 F.3d 47, 54 (2d Cir. 1995) (“The fact that the other defendants did not sell their shares during the relevant class period undermines plaintiffs’ claim that defendants delayed notifying the public ‘so that they could sell their stock at a huge profit.’” (quoting In re Cypress Semiconductor Sec. Litig., No. C-92-20048-RMW, 1992 WL 394927, at *2 (N.D. Cal. Sept. 23, 1992))).

In sum, the Amended Complaint does not plead facts demonstrating that Defendants’ stock sales are sufficiently suspicious or unusual so as to support a strong inference of scienter.

Plaintiffs next argue that Defendants had a motive to commit fraud because Evolus conducted a secondary offering of shares on November 6, 2019, providing the Company with net proceeds of \$63.5 million. (Am. Cmpl. (Dkt. No. 70) ¶ 17) “[A] desire to complete a successful public offering is not a ‘concrete benefit[] sufficient to demonstrate motive,’” however. Hawaii Structural Ironworkers Pension Tr. Fund v. AMC Ent. Holdings, Inc., 422 F. Supp. 3d 821, 848-49 (S.D.N.Y. 2019) (quoting Janbay v. Canadian Solar, Inc., No. 10 CIV. 4430, 2013 WL 1287326, at *10 (S.D.N.Y. Mar. 28, 2013)).

Acknowledging this case law, Plaintiffs argue that “[c]ourts have found allegations of motive adequate where the company needed to raise funds to survive.” (Pltf. Opp. (Dkt. No. 108) at 35 (citing Skiadas v. Acer Therapeutics Inc., No. 1:19-CV-6137-GHW, 2020 WL 3268495, at *11 (S.D.N.Y. June 16, 2020))) In support of their claim that Evolus needed the funds raised in the November 2019 public offering to survive, Plaintiffs cite the Company’s Form 10-K for 2019, which was filed on February 25, 2020. In its Form 10-K, Evolus states that it has “incurred losses in each year since [its] inception,” and that it “expect[s] to continue to incur losses for the foreseeable future.” (Fuks Decl., Ex. 2 (Evolus 2019 Form 10-K) (Dkt. No.

109-2) at 4) Elsewhere in the 10-K, however, Evolus states that it “anticipates that [its] existing cash, cash equivalents and investments will be sufficient to fund [its] current operating plan for the next twelve months.” (*Id.* at 5) In sum, the Amended Complaint does not plead facts sufficient to demonstrate that Evolus “needed to raise funds [in November 2019] for [the Company] to remain viable,” *Skiadas*, 2020 WL 3268495, at *11, and the November 6, 2019 public offering does not support a strong inference of scienter.

The Court concludes that the Amended Complaint does not plead facts demonstrating that Defendants had a motive to commit fraud.

b. Conscious Misbehavior and Recklessness

Given the Court’s finding that the Amended Complaint does not plead facts sufficient to demonstrate that Defendants had a motive to commit fraud, in order for Plaintiffs to establish scienter through conscious misbehavior or recklessness, “the strength of [their] circumstantial allegations must be . . . greater.” *Kalnit*, 264 F.3d at 142.

In asserting that Defendants acted recklessly, Plaintiffs contend that (1) Defendants were on notice of Medytox’s misappropriation allegations as of 2017, when the lawsuits were filed in California and South Korea; and (2) according to CW1, Evolus’s management refused to investigate the allegations of misappropriation. (Plft. Opp. (Dkt. No. 108) at 33-34)

CW1 was the Director of Medical Affairs at Evolus between October 2018 and November 2019 and reported to Defendant Avelar. (Am. Cmplt. (Dkt. No. 70) ¶ 122)

According to the Amended Complaint, CW1 has stated that

the Company did not investigate the allegations that Jouveau was the product of misappropriation. CW1 stated that the Company had no interest in investigating the incredible claim that Jouveau was discovered in the soil in Korea because it would not be beneficial for Evolus to know that Jouveau was misappropriated.

(Id. ¶ 126) Citing CW1’s allegations, Plaintiffs contend that “[a]n egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of . . . recklessness.” (Pltf. Opp. (Dkt. No. 108) at 33 (quoting Chill, 101 F.3d at 269))

Here, for reasons discussed above in connection with Defendants’ alleged false or misleading statements about the ITC litigation, CW1’s allegations do not support an inference of recklessness. While the Amended Complaint alleges that Defendants were aware of Medytox’s allegations of misappropriation prior to the ITC litigation, it does not allege that Defendants had seen evidence supporting these allegations. And while the Amended Complaint asserts that Daewoong’s claim that it had discovered its BTX strain “in the soil in Korea” was implausible, Plaintiffs do not allege facts showing that Defendants’ viewed Daewoong’s account as implausible. Nor would any implausibility in Daewoong’s account establish that Daewoong had misappropriated its BTX strain from Medytox.

As for Evolus’s alleged failure to investigate Medytox’s allegations of misappropriation, as discussed above, it is not clear what such an investigation would have yielded. Most of the materials and information that had a bearing on Medytox’s misappropriation allegations – including samples of Medytox’s BTX strain, details regarding Daewoong’s and Medytox’s manufacturing processes, and evidence regarding BK Lee’s employment at and relationship with Medytox and Daewoong – were in the possession of Daewoong and Medytox in South Korea and would have been difficult for Evolus to obtain. Accordingly, even if Defendants viewed Medytox’s misappropriation allegations as plausible – and the Amended Complaint does not plead facts suggesting that they did – the difficulty of investigating Medytox’s allegations undercuts Plaintiffs’ claim that Defendants acted recklessly in failing to do so.

As to the Individual Defendants’ state of mind, the Amended Complaint says nothing, citing only CW1’s conclusory and generic claim that “the Company had no interest in investigating” the misappropriation allegations. (Id. ¶ 126) Although CW1 reported directly to Avelar, CW1 provides no information about his or her interactions with Avelar – or any of the other Individual Defendants – regarding Medytox’s allegations. Absent such evidence, CW1’s conclusory assertion is not sufficient to demonstrate that any Individual Defendant had a culpable intent to “remain willfully ignorant” regarding the misappropriation allegations. See Glaser v. The9, Ltd., 772 F. Supp. 2d 573, 589-90 (S.D.N.Y. 2011) (“[E]ven confidential high level executives’ statements will be insufficient absent some allegation that the witness communicated with the individual defendants . . . or else that the witness was privy to the individual defendants’ knowledge.”). In sum, CW1’s allegations are not sufficient to support an inference of recklessness.

Plaintiffs argue, however, that Defendants “were aware [of] or recklessly disregarded” discovery produced during the ITC litigation indicating that Daewoong had misappropriated Medytox’s BTX strain. (Pltf. Opp. (Dkt. No. 108) at 29)

For the reasons discussed above in connection with Defendants’ opinion statements, this evidence does not give rise to an inference of recklessness. As discussed earlier, the Amended Complaint does not plead facts demonstrating that Defendants were aware of the discovery produced in the ITC litigation. And given the restrictions imposed by the ITC ALJ’s protective order – which barred Defendants from accessing all confidential business information produced in discovery, including, inter alia, the scientific evidence regarding the BTX strains and the details of Medytox’s manufacturing process – there is no reason to believe that Defendants were aware of the most critical information that had been produced during discovery. Plaintiffs’

assertion that Defendants somehow “‘must have educated’” themselves about this critical evidence (see Pltf. Opp. (Dkt. No. 108) at 33 (quoting In re Gen. Elec. Co., 857 F. Supp. 2d at 395) is mere speculation.

Plaintiffs also cite to the “core operations” doctrine (id. at 35-36), under which “a court may infer ‘that a company and its senior executives have knowledge of information concerning the core operations of a business,’ such as ‘events affecting a significant source of income.’” In re Supercom Inc. Sec. Litig., No. 15 CIV. 9650 (PGG), 2018 WL 4926442, at *31 (S.D.N.Y. Oct. 10, 2018) (quoting In re Express Scripts Holding Co. Sec. Litig., No. 16 CIV. 3338 (ER), 2017 WL 3278930, at *18 (S.D.N.Y. Aug. 1, 2017)) “[T]he core operations inference may be considered as part of a court’s holistic assessment of the scienter allegations, [but] . . . it is not independently sufficient to raise a strong inference of scienter.” Id. (quoting In re Rockwell Med., Inc. Sec. Litig., No. 16 CIV. 1691 (RJS), 2018 WL 1725553, at *15 (S.D.N.Y. Mar. 30, 2018)).

In any event, the “core operations” doctrine is not applicable here, given the restrictions imposed by the ITC ALJ’s protective order, which limited access to confidential business information to outside counsel. (See Rosenberg Decl., Ex. P (Mar. 5, 2019 ITC Prot. Order) (Dkt. No. 102-16) ¶¶ 1, 3) As discussed above, the limitation regarding access to confidential business information applied not only to discovery material, but also at the ITC evidentiary hearing. (Rosenberg Decl., Ex. V (Feb. 4, 2020 ITC Hrg. Tr.) (Dkt. No. 102-22) at 11, 18) While Defendants did have access to materials that did not constitute confidential business information, the Amended Complaint does not allege what the non-confidential material revealed about the merits of Medytox’s misappropriation claim and Evolus’s likelihood of success in the ITC litigation.

Plaintiffs argue that Evolus’s outside counsel “doubtlessly shared the import of the evidence with Defendants.” (Pltf. Opp. (Dkt. No. 108) at 30) As stated earlier, this is mere speculation, and such speculation is a particularly inappropriate basis for a recklessness finding here, given the ALJ’s protective order and the complexity of the confidential materials.

As an initial matter, the evidence that ultimately demonstrated misappropriation – i.e., the comparative genetic analysis, the review of Daewoong’s and Medytox’s manufacturing process, and the evidence of Daewoong’s development of DWP-450 prior to 2013 – required an analysis of competing expert testimony and voluminous confidential records. The complexity of this material is conveyed by the length of that portion of the ALJ’s decision announcing his findings: 40 pages. (Am. Cmplt., Ex. B (July 6, 2020 FID, Public Version) (Dkt. No. 70-2) at 99-117, 137-59)

And there were many other complex and contested issues in the ITC litigation. For example, the parties vigorously disputed whether Medytox’s BTX strain and manufacturing process constituted protectable trade secrets. Evolus also raised a variety of jurisdictional issues and affirmative defenses. And while the ITC ALJ agreed with Medytox and Allergan on the trade secret issue, the ITC reversed that determination. Suffice it to say that Evolus’s outside counsel would have had a good faith reason to believe that Medytox’s BTX strain was not a protectable trade secret. In sum, while Evolus did not ultimately prevail on every issue in the ITC litigation, the Amended Complaint does not plead facts demonstrating that Defendants did not have a reasonable, good faith belief in their likelihood of success before the ITC.

The Court concludes that the materials made available to Defendants during the ITC litigation do not provide a basis for a finding of recklessness.¹¹

c. Holistic Assessment

Although this Court has rejected all of Plaintiffs' scienter arguments individually, it must consider whether the allegations "give rise to a strong inference of scienter" when "taken collectively." Tellabs, 551 U.S. at 322-23. As discussed above, the Amended Complaint "will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. at 324.

As discussed above, Plaintiffs have not provided any basis for this Court to conclude that Defendants had a motive to commit fraud, and Plaintiffs' allegations of conscious misbehavior and recklessness are likewise unsupported. Even when Plaintiffs' allegations of scienter are viewed collectively, Plaintiffs have failed to demonstrate that the inference of scienter is more cogent and compelling than the non-culpable inference – namely, that Defendants expressed confidence in Evolus's position in the ITC litigation because they had a reasonable, good faith belief the Company would ultimately prevail.

Because the inference that Defendants acted recklessly is less plausible than the non-culpable inference, Plaintiffs have not sufficiently alleged scienter with respect to Defendants' statements. Tellabs, 551 U.S. at 324

* * * *

¹¹ Plaintiffs also contend – without explanation – that "the Individual Defendants' prior employment at Allergan provided them with actual knowledge that the misappropriation allegations were not meritless." (Pltf. Opp. (Dkt. No. 108) at 37) The alleged misappropriation took place in South Korea, however, and involved employees of Daewoong and Medytox. It has no apparent connection to Allergan, and Plaintiffs do not explain why the Individual Defendants' prior employment at Allergan would have given them insight into the truth of the misappropriation allegations.

For all the reasons discussed above, Plaintiffs' claim under Section 10(b) of the Exchange Act and Rule 10b-5 will be dismissed.

III. CONTROL PERSON LIABILITY

The Amended Complaint asserts claims against Defendants for violations of Section 20(a) of the Exchange Act. (Am. Cmplt. (Dkt. No. 70) ¶¶ 264, 270) Claims for control person liability under Section 20(a) are “necessarily predicated on a primary violation of the securities law[s].” Rombach, 355 F.3d at 177-78. Because Plaintiffs have not adequately pleaded an underlying violation of the securities laws, their Section 20(a) claims will likewise be dismissed.¹²

IV. INSIDER TRADING CLAIM UNDER SECTION 20A

Plaintiffs bring an insider trading claim against Defendant Alphaeon under Section 20A of the Exchange Act in connection with Alphaeon's May 20, 2019 sale of approximately four million shares of Evolus stock. (Am. Cmplt. (Dkt. No. 70) ¶¶ 283, 287)

Section 20A(a) of the Exchange Act creates a private right of action to address insider trading, and states that

[a]ny person who violates any provision of [the Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class.

15 U.S.C. § 78t-1(a). To state a claim under Section 20A(a), a plaintiff must “(1) plead a predicate insider trading violation of the Exchange Act, and (2) allege sufficient facts showing

¹² Because Plaintiffs' Section 20(a) claim will be dismissed because of their failure to plead a primary violation of the Exchange Act, this Court does not reach Defendant Alphaeon's argument that the Amended Complaint fails to plead facts demonstrating that it exercised control over Evolus (Alphaeon Br. (Dkt. No. 104) at 22-23), or that Alphaeon acted with “culpable participation” in the alleged fraud. (Id. at 23-26)

that the defendant traded the security at issue contemporaneously with the plaintiff.” In re Take-Two Interactive Sec. Litig., 551 F. Supp. 2d 247, 304 (S.D.N.Y. 2008) (quotation marks and internal citations omitted).

Here, the Amended Complaint alleges that

[b]y virtue of [Alphaeon’s] members on Evolus’s Board of Directors, who were also members of Evolus’s Audit Committee, Corporate Governance Committee and Compensation Committee and were also members of Alphaeon’s Board of Directors, Alphaeon had access to the Company’s material non-public information and was aware of and/or recklessly disregarded the evidence demonstrating that Jeuveau was the product of misappropriation.

(Am. Cmpl’t. (Dkt. No. 70) ¶ 289)

As discussed above, the Amended Complaint also alleges that Defendants became aware of the truth of the misappropriation allegations as a result of (1) discovery produced in the ITC litigation; and (2) disclosures at the February 2020 ITC evidentiary hearing. (Id. ¶¶ 195, 207)

Alphaeon’s sale of four million Evolus shares took place on May 20, 2019, about two and a half months after the ITC’s March 1, 2019 announcement that it would initiate an investigation of Allergan and Medytox’s misappropriation allegations. (Id. ¶ 10) The sale thus occurred prior to the close of fact discovery on July 19, 2019, and prior to the close of expert discovery on October 30, 2019. (Id. ¶ 13) Moreover, as discussed above, the ITC ALJ’s protective order prohibited Evolus’s outside counsel from sharing the contents of confidential business information. Given these circumstances, there is no reason to believe that evidence demonstrating that Daewoong had misappropriated Medytox’s BTX strain and its manufacturing process would have been shared with Alphaeon. In any event, the Amended Complaint does not plead facts demonstrating that – at any stage of the ITC case – representatives of Alphaeon were aware of discovery material produced in the ITC litigation or evidence offered at the February

2020 evidentiary hearing. Accordingly, the Amended Complaint does not plausibly allege that Defendant Alphaeon was in possession of material non-public information at the time it sold Evolus stock in May 2019.

Accordingly, Plaintiff's claim under Section 20A of the Exchange Act will be dismissed.

CONCLUSION

For the reasons stated above, Defendants' motions to dismiss the Amended Complaint (Dkt. Nos. 100, 103) are granted.

While the Court grants leave to move to amend, in any such motion, Plaintiff will explain in detail how each defect cited in this Opinion has been satisfied by new factual allegations in the proposed second amended complaint. Any motion for leave to amend is to be filed by **October 17, 2024**. The proposed second amended complaint is to be attached as an exhibit to the motion.

The Clerk of Court is directed to terminate the motions (Dkt. Nos. 100, 103).

Dated: New York, New York
September 26, 2024

SO ORDERED.

A handwritten signature in black ink, reading "Paul G. Gardephe", written in a cursive style.

Paul G. Gardephe
United States District Judge